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NATIONAL HEART TRANSPLANTATION STUDY

VOLUME 3.

SURVIVAL
QUALITY OF LIFE
COST OF HEART TRANSPLANTATION

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CHAPTER 20

AN OVERVIEW OF SURVIVAL ANALYSIS

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A. INTRODUCTION

The survival benefit from heart transplantation has been debated in the medical and statistical literature since the first such operation was performed by Dr. Christiaan Barnard in South Africa. In this country heart transplantation was pursued vigorously in the late 1960's, especially by teams in Houston and at the Stanford University Medical Center. Data from the Stanford group were first summarized by Clark et al. (1971), who presented survival curves reflecting the posttransplant experience of their patients. They presented as well a comparison of that experience with the survival of candidates who were accepted by the program but died before receiving a new heart.

This report illustrates the dilemma inherent in any assessment of the costs and benefits of heart transplantation. An important part of the assessment is an analysis of posttransplant survival and how survival is affected by such factors as age and histocompatibility. Such an analysis is outlined below and detailed in Chapter 21. However, another important question is whether there is an improvement in survival posttransplant compared to what could be expected without the operation. This is a very difficult question to answer. Gail (1972), has pointed out, for example, that a simple comparison of posttransplant survival to the experience of accepted candidates who died before receiving a heart is not valid. He argues such a comparison could be nothing more than one between patients hardy enough to survive the waiting period for a donor heart and those who die first and are thus, by definition, less hardy initially. In the

absence of a randomized trial a more sophisticated statistical approach is required, as we detail below.

B. POSTTRANSPLANT SURVIVAL

The Stanford group has published a series of papers on the survival of their patients after transplantation (Schroeder et al., 1976; Griepp et al., 1977; Jamieson et al., 1979). The gist of these publications is that there is an increasing trend in posttransplant survival with calendar time, based on comparisons of the survival curves of cohorts of patients transplanted in different time periods. Explanations advanced involve improved post-operative treatment, including the relatively recent addition of cyclosporine to help avoid rejection of the donor heart.

There are other reasons why there might be such a trend, however. In particular, a trend toward accepting patients with better prognosis would produce the same result, and this indeed seems to have happened, at least as regards age at acceptance (Kalbfleisch and Prentice, 1980). There is thus a need for a regression approach to identify which types of patients (and from which institutions) have the best posttransplant survival experience, and to determine whether or not the improvement in results can be attributed largely to patient selection.

The fact that the data are analyzed before all patients have died means that the survival times for some are not known exactly but are known only to be greater than the patient's follow-up time. These so-called censored observations necessitate a different approach to

regression from the classical least-squares line. Several generalizations of least-squares regression have, in fact, been proposed and tried on the Stanford heart transplant data (Miller, 1976; Miller and Halpern, 1981; Buckley and James, 1979; and Koul, Susarla, and Van Ryzin, 1981). But the more common approach to censored survival data involves direct modelling of the hazard function, which is the risk of death as a function of time. The general formulation involves specifying the hazard for an individual with covariates Z (age, sex, etc.) as

$$\lambda(t)\, f(\beta Z) ,$$

where f is a specified function and β is a vector of regression parameters to be estimated. A common choice of f is

$$f(\beta Z) = \exp(\beta Z) ,$$

implying multiplicative effects of covariates on the risk; this form is also particularly convenient statistically.

The baseline (for values of the covariates Z=0) hazard $\lambda(t)$ can be modelled using a family of functions specified by one or more parameters, or left largely arbitrary. Examples of the former are the exponential family, given by $\lambda(t)=\lambda$ (a constant) and the Weibull, given by $\lambda(t)=p\lambda t^{p-1}$. The exponential model was used by Beck (1979) and the Weibull by Aitkin, Laird, and Francis (1983) to model posttransplant survival; there are of course other possibilities, some contained in the last reference. The model used here leaves $\lambda(t)$ unspecified, minimizing difficulties of goodness-of-fit but retaining

high precision of estimation. This method was pioneered by Cox (1972) and was used in the context of posttransplant survival by Crowley and Hu (1977).

Thus we will model the risk of death, as a function of time after transplantation, as $\lambda(t) \exp(\beta Z)$. The influence of covariates such as age and sex on this risk can be assessed via estimates of the regression coefficients β and estimated standard errors, using the partial likelihood (Cox, 1975). The underlying hazard (or rather its integral) can be estimated as described in Breslow (1974). The special case of a homogeneous group of patients is treated by estimating a single survival curve by the method of Kaplan and Meier (1958).

The covariates to be considered for their impact on survival include sex, race (white vs. other), transplant period (1968-1973, 1974-1979, 1980-1983), age at transplant, and level of functional impairment (as measured by the Karnofsky Index).

C. COMPARISON OF PRE- AND POSTTRANSPLANT SURVIVAL

There is no simple answer to the question of how to assess whether heart transplantation increases or decreases the risk of death. The clearest evidence would be derived from a randomized trial, but this does not appear to be possible. A simple comparison of posttransplant survival to the survival of accepted candidates not receiving a donor heart is biased, for reasons described above. The only feasible method at present is to develop a statistical model for the risk of

death as a function of time from acceptance as a candidate for heart transplantation, and to assess the change in that risk after the transplant.

To this end let the risk of death as a function of time from acceptance into the program be denoted

$$\lambda_2(t) \exp(\beta_2 Z_2) \quad ;$$

and let the "risk" or rate of arrival of a donor heart be

$$\lambda_1(t) \exp(\beta_1 Z_1)$$

(which may in fact not depend on any patient characteristics). The risk of death after the transplant might well be a function of both waiting time from acceptance to transplant t_w and time from transplant $t-t_w$ and thus in greatest generality would be expressed as

$$\lambda_3(t_w,t) \exp(\beta_3 Z_3) \quad .$$

The covariates to be considered (Z_1, Z_2, Z_3) include those described previously, as well as some reflecting patient characteristics at acceptance. The comparison of post- and pretransplant survival is then summarized in the ratio, or relative risk,

$$\frac{\lambda_3(t_w,t) \exp(\beta_3 Z_3)}{\lambda_2(t) \exp(\beta_2 Z_2)} \quad .$$

Values less than one indicate a decreased risk, or increased survival, after transplant. This ratio could thus depend on the covariates influencing pre-transplant survival (Z_2), those affecting

posttransplant survival (Z_3), and the waiting time t_w. The ratio could also be more than one for a period, then less than one, making simple comparisons difficult.

As in the analysis of posttransplant survival, the hazard functions may be assumed to be from particular parametric families (Turnbull, Brown, and Hu, 1974; Aitkin, Laird, and Francis, 1983) or may be left arbitrary, the approach adopted here, as in Crowley and Hu (1977).

In either case, particular simplification is provided if, to a reasonable approximation,

$$\lambda_3(t_w, t) \exp(\beta_3 Z_3) = \lambda_2(t) \exp(\beta_0 + \beta'_3 Z_3 + \alpha t_w) \quad ,$$

so that the relative risk, post- to pretransplant, is a single number,

$$\exp(\beta_0 + \beta'_3 Z_3 - \beta_2 Z_2 + \alpha t_w) \quad .$$

Further parsimony is achieved if $\alpha = 0$; that is, if waiting time to transplant does not affect posttransplant risk. Then a simple expression for a given patient gives the effect of the transplant on survival, positive or negative. These sub-models will be of particular focus in our analyses: we will fit models using the partial likelihood which allow us to assess the goodness-of-fit of the more parsimonious submodels.

The ultimate goal is to arrive at a description of the data which summarizes the effect of transplantation on survival. This may be a function of the covariates mentioned in the previous section, as well as the time from acceptance to transplantation. Tables will be

derived which give the estimated benefit (or deficit) in risk of death following transplantation for patients with various characteristics. These tables can then be used to weigh the benefits against the cost as an aid in determining reimbursement policy.

D. CONCLUSION

Clearly, as described here, there are many issues that remain to be resolved concerning the survival of persons who receive transplants as well as those who do not. On the one hand, the statistical literature has argued that relatively little net survival benefit is derived from heart transplantation. Yet, on the other hand, the surgical literature shows that heart transplant recipients survive in ever increasing numbers for extended periods of time. Survival rates for one through five years have continued to improve. The statisticians contend, however, that a selection bias is introduced when patients are chosen as heart transplant recipients. In effect, patients who are less healthy die before receiving a heart transplant. Thus, based on the foregoing, it is important that recent data are analyzed to re-examine the issue of whether or not heart transplantation prolongs life. A preliminary analysis of the data is pursued in Chapter 22 to shed further light on this matter. Further analyses of these data are required, however, before the issue can be resolved satisfactorily. In the absence of a prospective randomized trial, it is inordinately difficult to reach a definitive conclusion.

The second issue that must be addressed is of more limited scope and concerns only those patients who have received heart transplants.

Often survival is depicted in a simplistic fashion through the use of actuarial survival curves. On only a rare occasion is survival discussed as an outcome that is determined by multiple variables. In other words, patient survival is affected by variables other than heart transplantation itself. In Chapter 21, Crowley and Yagi use a rather sophisticated Cox proportional hazards model to determine which, if any, other variables are related in a statistically significant way with patient survival. In particular, they examine the relationship of the following variables to patient survival: sex, race, transplant period, age at transplant, and level of functional impairment before heart transplant. They clearly show that survival is affected by numerous other factors. The results show that younger, healthier patients who have been transplanted in the period 1980-1983 have a longer survival time than other patients. This suggests that patient selection is an important determinant of survival and that genuine advances have been made in transplantation technology.

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CHAPTER 21

SURVIVAL OF HEART TRANSPLANT RECIPIENTS

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A. INTRODUCTION

As noted in Chapter 20, the Cox proportional hazards model has been used to analyze the survival experience of heart transplant recipients. This technique is far more sophisticated than other techniques available for the analysis of survival data.

The primary objective of this Chapter is to determine what effect, if any, several clinical and sociodemographic covariates (e.g., age, sex, level of functional impairment prior to transplantation) have on the survival of heart transplant recipients. In addition, however, attention is also directed to the relative risk of mortality among transplant recipients as a function of various clinical and sociodemographic variables. Finally, survival curves are computed for various subgroups of patients and for different transplant periods.

B. LITERATURE REVIEW

Since the early 1970's the Stanford heart transplant data have been periodically analyzed by statisticians and clinicians alike (Clark et al., 1971; Schroeder et al., 1976; Griepp et al., 1977; Turnbull et al., 1974; Crowley and Hu, 1977; Kalbfleish and Prentice, 1980). Many of the early analyses of these data by clinicians failed to incorporate an appropriate control group to facilitate the examination of potential biases in the selection of transplant recipients. As described in Chapter 20, the statisticians have been highly critical of existing clinical reports because it is felt that heart transplant recipients are a very biased group to study--they, unlike their peers with end-stage cardiac disease, have managed to

survive long enough to receive a transplant. Table 21-1 summarizes the characteristics of control groups used in previous analyses of the heart transplant data.

Clark and associates (1971) compared the survival of transplant recipients with that of nontransplant recipients for the period between July, 1967 and March, 1970. Nontransplant patients were those who had been selected for cardiac transplantation but died awaiting a donor heart. However, as noted by Gail (1972), under this definition, the nontransplanted patients naturally constitute a very high risk group. In fact, Gail went so far as to suggest that the apparent advantage attributed to transplantation by Clark et al. and others, may be due entirely to this selection bias. Because of this, Schroeder et al., (1976), Griepp et al., (1977) and others eliminated the comparison group from their analyses. In doing so, however, they sacrificed their ability to ascertain the life prolonging effects of heart transplantation, even though their analyses were useful in the examination of the post-transplant survival experiences of heart transplant recipients.

Turnbull et al. (1974), as well as other statisticians, subsequently redefined the control group. This was accomplished by including the pre-transplant survival of transplanted patients in estimating the survival of nontransplanted patients. In these analyses, transplant is treated as a censoring mechanism. Crowley and Hu (1977), using a proportional hazards model, which permits one to take time dependent covariates into account, found no significant difference between the survival experiences of the control group

Table 21-1
Summary of the Characteristics of Previous Control Groups Used
In The Analysis of the Stanford Heart Transplant Data

1. NO CONTROL
   (Transplant Recipients)
   . Schroeder et al., 1976; Griepp et al., 1977.

2. CONTROL-TYPE 1
   (Non-recipients)
   . Clark et al., 1971
   . Gail, 1972 - selection bias

3. CONTROL-TYPE 2
   (Non-recipients + pre-transplant patient's survival experience)
   . Turnbull, Brown, and Hu, 1974; Mantel and Byer, 1974
   . Crowley and Hu, 1977
   . Kalbfleish and Prentice, 1980

patients when compared with the transplanted patients. Similarly, Kalbfleish and Prentice (1980) reanalyzed the Stanford heart transplant data and found a possible positive effect of transplantation for a younger group of patients (46 years old and younger) using a control group similar to that used by Crowley and Hu.

C. THE MODEL

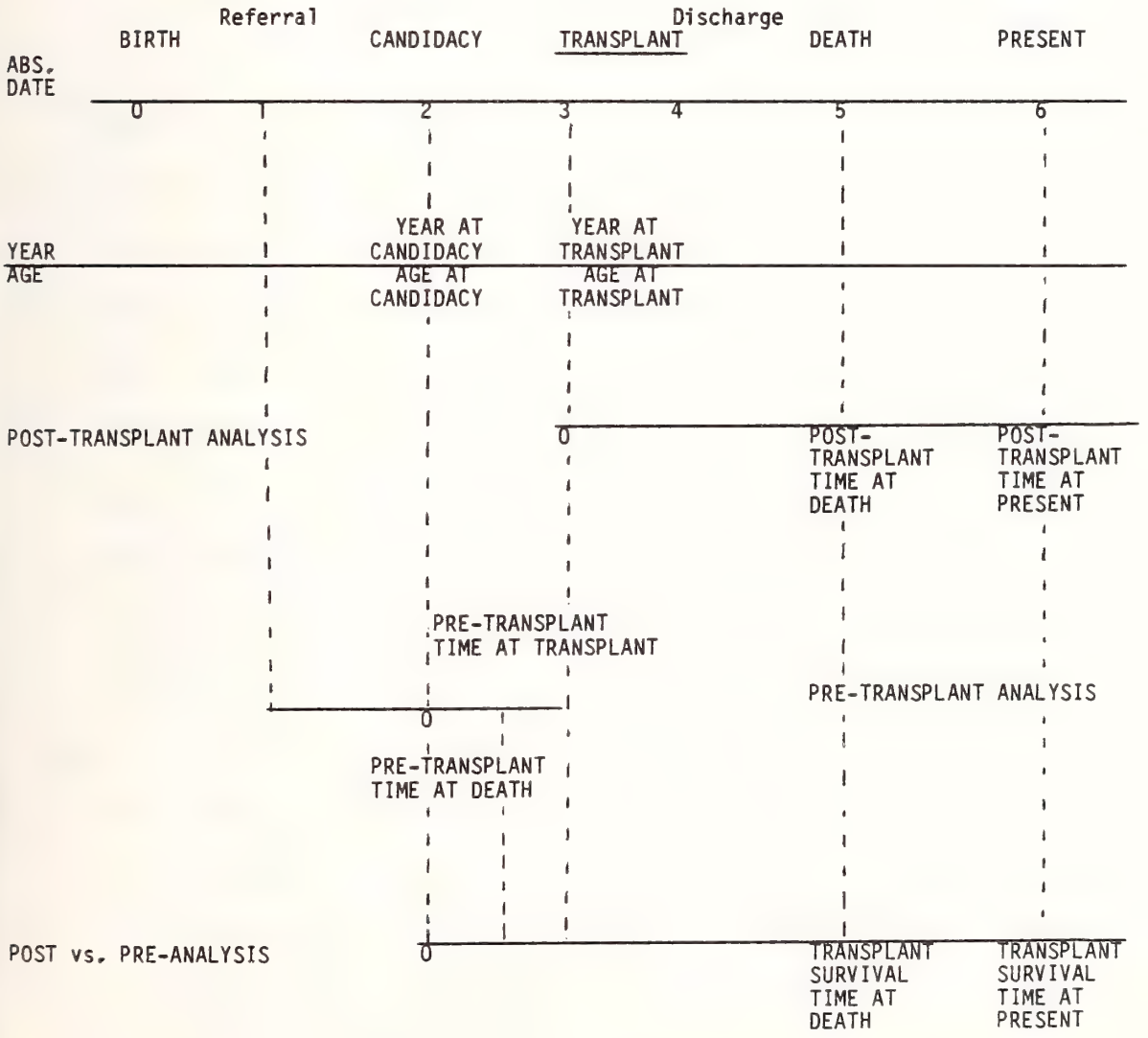
Time is obviously one of the key variables in the analysis of survival data. However, to analyze the data properly, numerous dates were abstracted from the medical and hospital records of each patient and were included in the analyses. These dates were as follows:

- date the form was completed
- date of referral
- date of birth
- date the patient's evaluation began
- date the patient's evaluation ended
- date of the candidacy decision
- date the patient became a candidate
- date of transplant
- date of discharge from the hospital
- date of death

The diagram presented in Figure 21-1 displays the sequence of the relevant dates along the time axis. The importance of year of transplant, year of candidacy, age at transplant, and age at candidacy

Figure 21-1
Heart Transplant Survival Analysis: Time

Question No.	Relevant Dates For Survival Analysis
0	Date the questionnaire was completed
4	Date of referral
8	Date of bithh
33	Date the patient's evaluation began
35	Date the patient's evaluation ended
37	Date of the candidacy decision
44	Date the patient became a candidate
77	Date of transplant
78	Date of discharge from the hospital
91	Date of death



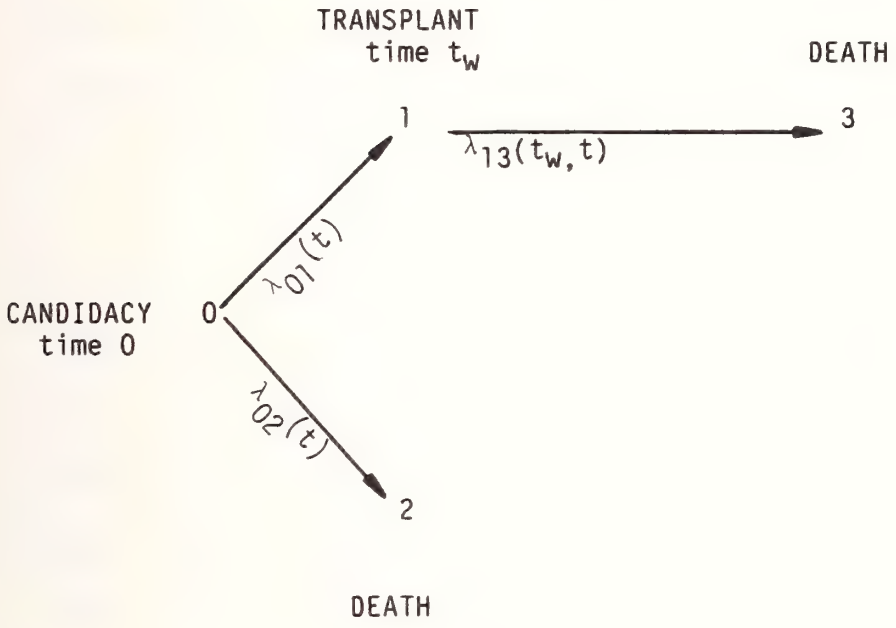
should be emphasized, since they will be used to adjust for both period and age effects upon the survival experience of the patients.

Figure 21-2 graphically depicts the transition force between the possible states for patients as time passes. Patients start at candidacy (state 0) and either progress to death (state 2) at a rate of $\lambda_{02}(t)$ after t units of time, or progress to transplant (state 1) at a rate of $\lambda_{01}(t)$ after t units of time. Transplant recipients with t_w units of waiting time progress to death (state 3) at an average rate of $\lambda_{13}(t_w,t)$ t units of time after being accepted as a candidate.

By imposing Cox-type semiparametric models on the intensities $\lambda_{ij}(t)$, where the effects of the covariates are proportional to baseline intensities, it is possible to develop the five proportional hazards models listed at the bottom of Figure 21-2. These models are then useful for conducting four different survival analyses. They are: posttransplant analysis, pre-transplant analysis, waiting time analysis, and post- vs. pre-transplant analysis. The first model--the post-transplant analysis--specifies that an instantaneous mortality rate $(t-t_w)$ units of time after transplantation with covariates z (hereafter, z is a vector) is proportional to the hazard for baseline individuals ($z = \underline{0}$). The model indicates that the covariates act multiplicatively on the baseline mortality hazard function, where the covariates could be time-dependent. The ratio of mortality rates, $\exp \beta \cdot (z_1 - z_0)$ defines a relative risk function measured at time t relative to individuals characterized by z_0. The results of

Figure 21-2
Heart Transplant Survival Analysis: Model

TRANSITION FORCE BETWEEN THE POSSIBLE STATES



Patients start at CANDIDACY (state 0) and either progress to DEATH (state 2) at a rate of $\lambda_{02}(t)$ after t units of time, or progress to TRANSPLANT (state 1) at a rate of $\lambda_{01}(t)$ after t units of time. Transplant recipients with t_w units of waiting time progress to DEATH (state 3) at an average rate of $\lambda_{13}(t_w,t)$, t units of time after being accepted as a candidate.

No.	Model	Analysis
1	$\lambda_{13}(t-t_w:\bar{z}) = \lambda_{13}(t-t_w)\cdot\exp(\beta_1\bar{z})$	Post-transplant
2	$\lambda_{02}(t:\bar{z}) = \lambda_{02}(t)\cdot\exp(\beta_2\bar{z})$	Pre-transplant
3	$\lambda_{13}(t_w,t) = \lambda_{13}(t)\cdot\exp(\beta_3 t_w)$	Waiting time
4	$\lambda_{13}(t:\bar{z}) = \lambda_{02}(t)\cdot\exp(\beta_4\bar{z})$	Post vs. Pre
5	$\lambda_{13}(t_w,t:\bar{z}) = \lambda_{02}(t)\cdot\exp(\beta_5\bar{z}+\beta_6 t_w)$	Post vs. Pre

this analysis are reported in this Chapter. The pre-transplant analysis (Model 2) and the waiting time analysis (Model 3) have not yet been conducted and are, therefore, not reported here.

The fourth and fifth proportional hazards models constitute the post- vs. pre-transplant analysis. This analysis is designed to answer the basic question of whether or not heart transplantation prolongs a patient's life expectancy, when compared to his/her expectancy otherwise. This analysis is currently in progress and is highlighted in Chapter 22.

Recipients' pre-transplant survival experiences can be incorporated into the proportional hazards model by using a time dependent transplant covariate. The variable remains at the non-recipient state (0) until the individual receives a heart transplant, at which time the variable changes to the recipient state (1). Figure 21-3 shows how the time dependent transplant status characteristic variable is included in the model.

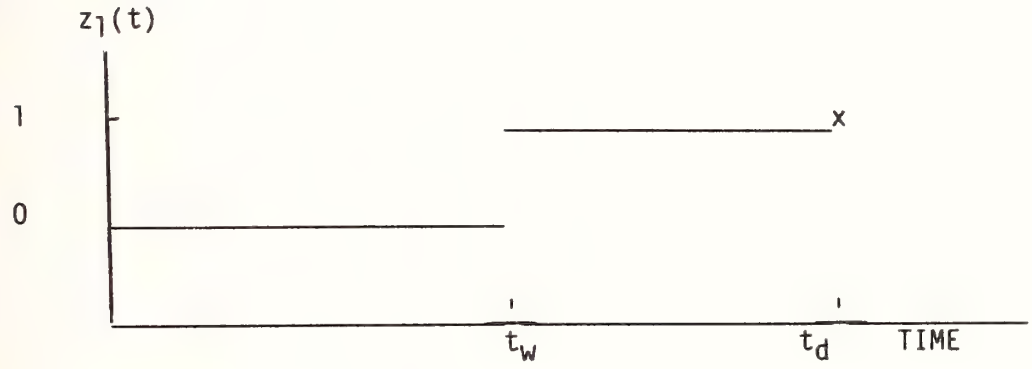
The current consensus is that the Cox proportional hazards model, with transplant status as a time-dependent covariate, is the most powerful method available for the analysis of heart transplant survival data. A proportional hazards model is partially nonparametric in that no assumptions are made regarding the functional form of the baseline hazard functions, whereas the multiplier is parameterized linearly in a logarithmic scale. Its semiparametric nature makes it possible to control for known or potentially confounding effects of concomitant factors simultaneously, while producing bias-free estimates of the coefficients of interest.

Figure 21-3
Time Dependent Transplant Status

$$\lambda(t:\bar{z}_1(t),\underline{z})=\lambda_0(t)\cdot\exp(\beta_1\bar{z}_1(t)+\beta\underline{z})$$

Suppose the ith patient is a recipient.
Then

$$z_1^i(t) = \begin{cases} 1 \text{ , after transplantation} \\ 0 \text{ , before transplantation} \end{cases}$$



In addition to age at transplant, possible covariates for the survival analysis include:

- transplant center
- sex
- race
- diagnosis
- functional impairment prior to transplantation (Karnofsky Index)
- number of antigen matches
- immunosuppressive drugs after surgery

A more detailed description of possible covariates for the heart transplant recipient survival analysis, including a specification of the corresponding value codes, is presented in Appendix 21-A.

Examples of how these variables may be grouped for analysis are presented in Appendix 21-B. For example, the transplant center variable is forced to be a binary code: non-Stanford and Stanford. This allows us to compare the results of the preceding Stanford heart transplant survival studies with the current study. Year of transplant is grouped in three categories. Hereafter this variable is referred to as transplant period and consists of three periods: 1968 to 1973, 1974 to 1979, and 1980 to 1983. The reason for this is twofold. First, the immunosuppressive drug, cyclosporine, was introduced in 1980 and, second, considerable technological advancements in heart transplantation have occurred since 1973. The Karnofsky Index is used to measure a patient's functional impairment prior to transplantation.

A score of one on this index stands for normal ability to function physically, while larger scores represent increasingly worse functional ability. Race is also forced to be binary because of the small numbers of patients in the non-white subcategories.

As with most multivariate statistical techniques, estimation of the proportional hazards model is hampered by missing data for one or more covariates included in the model. The larger the number of explanatory variables included, the greater the chance that missing data may hinder the analysis. A summary of the missing values of the major variables included in the survival analysis is presented in Appendix 21-C. Among the possible covariates, race, diagnosis, functional impairment prior to transplantation, cyclosporine, and HLA-matches variables were missing from some patients. When these five covariates are included in the full or reduced models, 62 out of a total of 420 observations are excluded from the analysis. If the HLA-matches variable is deleted, then only 11 observations are excluded. The loss of these cases for analysis is assumed not to affect the results.

D. DESCRIPTIVE STATISTICAL RESULTS

In general, the variables in the transplant survival analysis can be placed into one of three categories: (1) time variables, (2) sociodemographic variables, and (3) clinical variables. A summary of these variables is presented in Table 21-2. The time variables consist of post-transplant time, pre-transplant time, waiting time, and patient survival time.

Table 21-2
Classification of Heart Transplant
Survival Analysis Variables

I. TIME VARIABLES

- POST-TRANSPLANT TIME AT PRESENT
- POST-TRANSPLANT TIME AT DEATH
- PATIENT SURVIVAL TIME AT DEATH
- PATIENT SURVIVAL TIME AT PRESENT
- WAITING TIME/PRE-TRANSPLANT TIME AT TRANSPLANT

II. SOCIODEMOGRAPHIC VARIABLES

- SEX
- RACE
- YEAR OF TRANSPLANT
- YEAR OF CANDIDACY
- AGE AT TRANSPLANT
- AGE AT CANDIDACY

III. CLINICAL VARIABLES

- DIAGNOSIS
- FUNCTIONAL ABILITY AT TIME OF EVALUATION
- FUNCTIONAL ABILITY AT TIME OF TRANSPLANT
- NUMBER OF ANTIGEN MATCHES
- IMMUNOSUPPRESSIVE DRUGS AFTER SURGERY
- NUMBER OF HEART TRANSPLANTS

A histogram of post-transplant time for the transplant recipients included in the study is presented in Figure 21-4. The mean post-transplant time (the time from the transplant operation until their death or the time of the study) is 705.5 days. However, some caution must be exercised in interpreting Figure 21-4, since not all of the end-points of the post-transplant time interval are at the patients death (i.e., some patients were still alive at the time of the study). Thus, this histogram is not a true survival curve.

Histograms showing patient survival time, year of transplant, and age at transplant are presented in Figures 21-5 through 21-7, respectively. Histograms of other time variables (waiting time, year of candidacy and age at candidacy) are presented in Appendix 21-D. In the case of transplant recipients, patient survival time (Figure 21-5), is similar to post-transplant time, except that it is measured from the beginning of candidacy rather than from the time of transplant. Thus, since it includes the candidacy period, the mean (745.7 days) is longer than for the post-transplant period. Again, because the survival time variable does not always end with a patient's death, Figure 21-5 is not a true survival curve.

With respect to year of transplant, Figure 21-6 shows that most of the transplant recipients included in the study received their transplants since 1980. In addition, as can be seen in Figure 21-7, the mean age of transplant recipients at the time they received their transplant was 39.7 years. Finally, the number of transplants performed increased monotonically to age 50, then a drop occurred

Figure 21-4
Post-Transplant Time For Heart Transplant Recipients

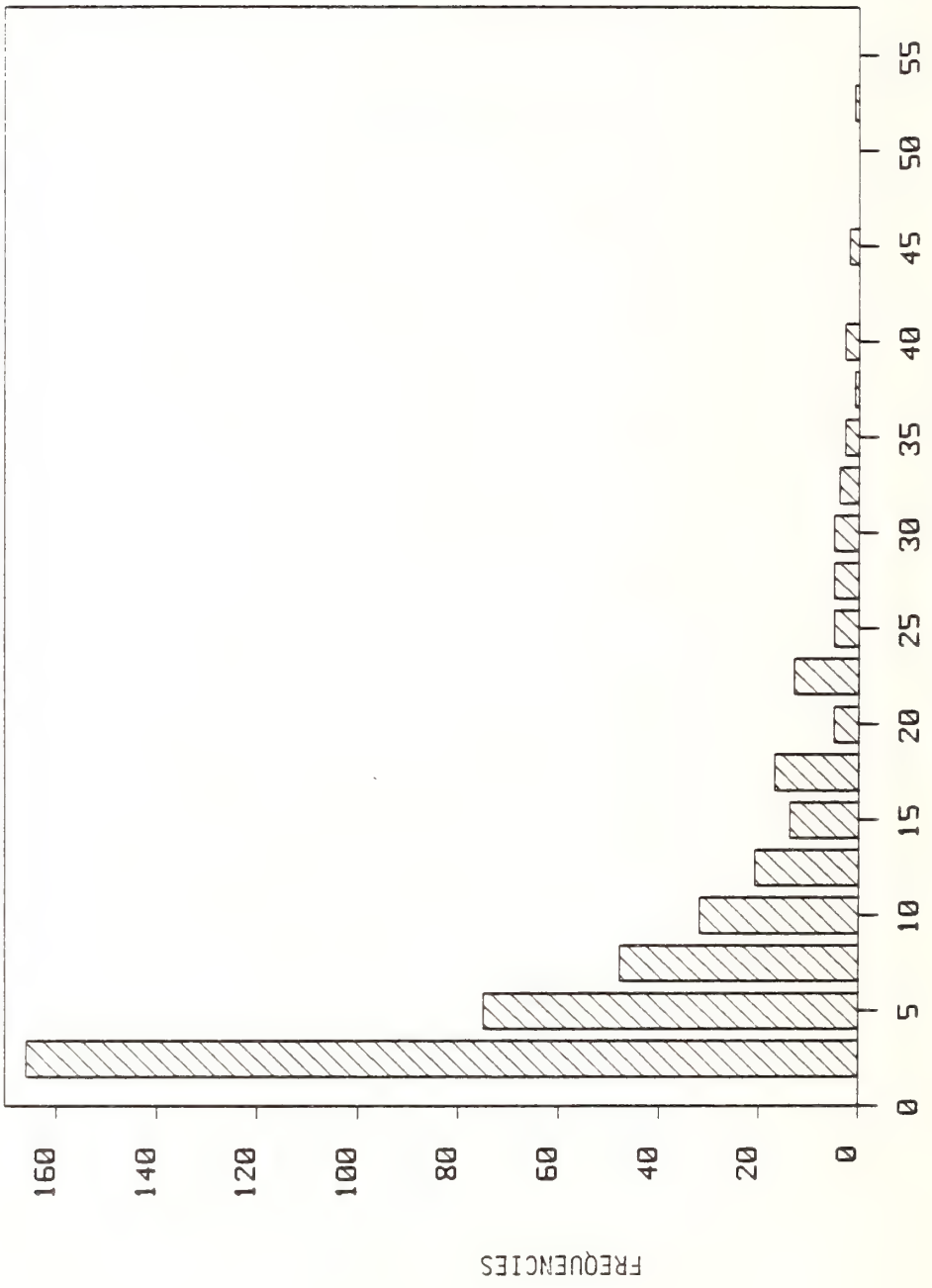
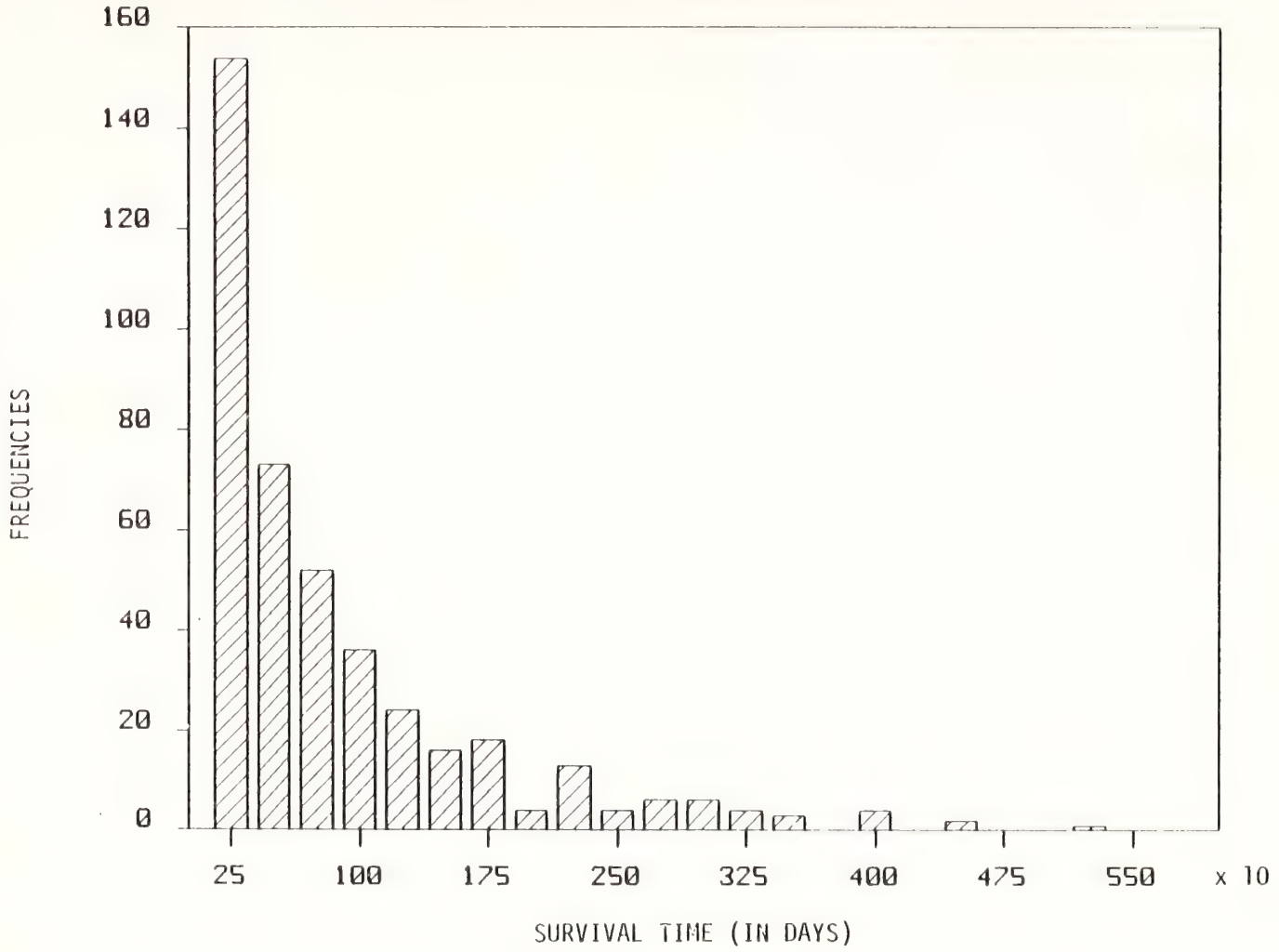


Figure 21-5
Survival Time of Heart Transplant Recipients



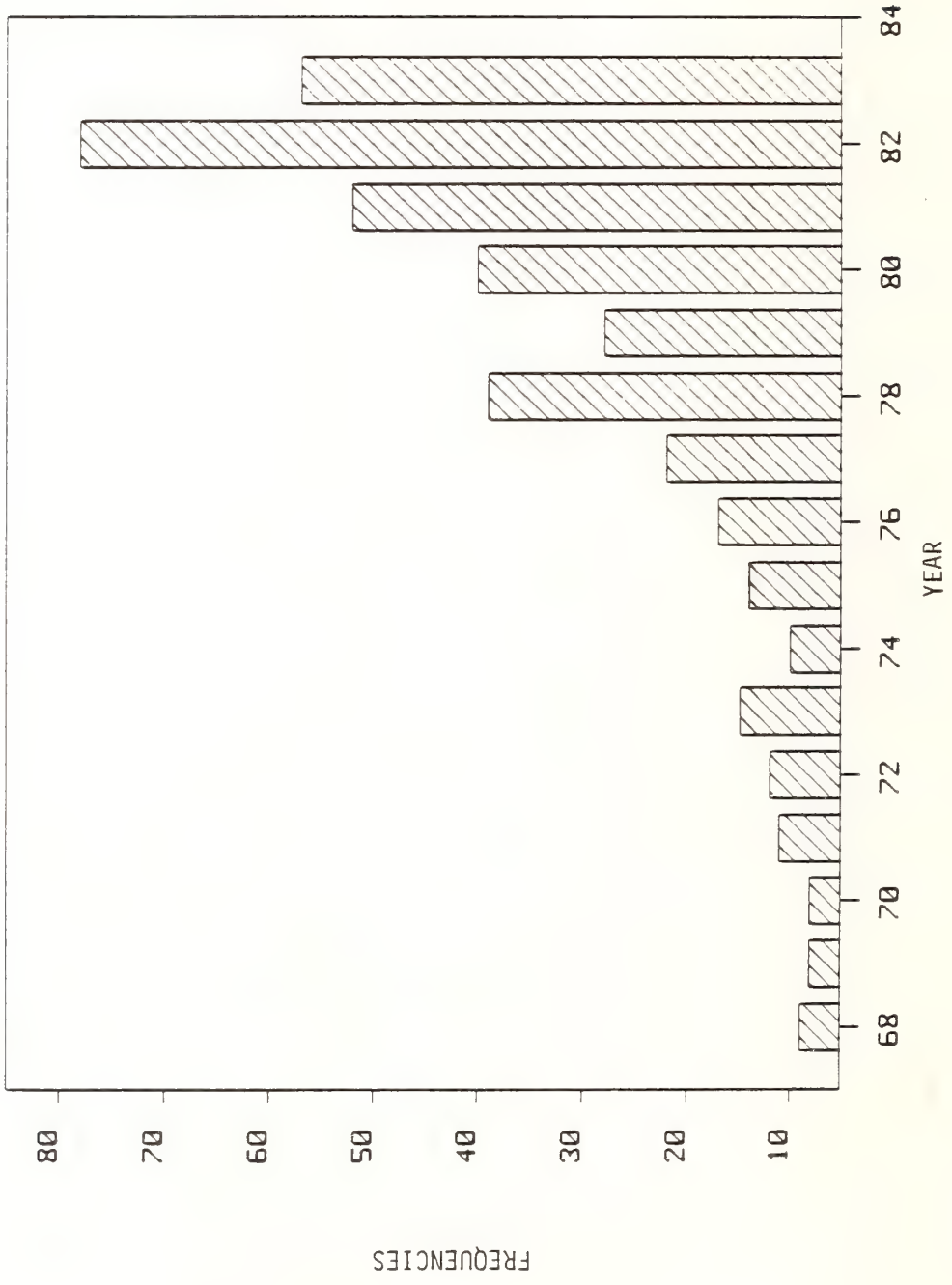
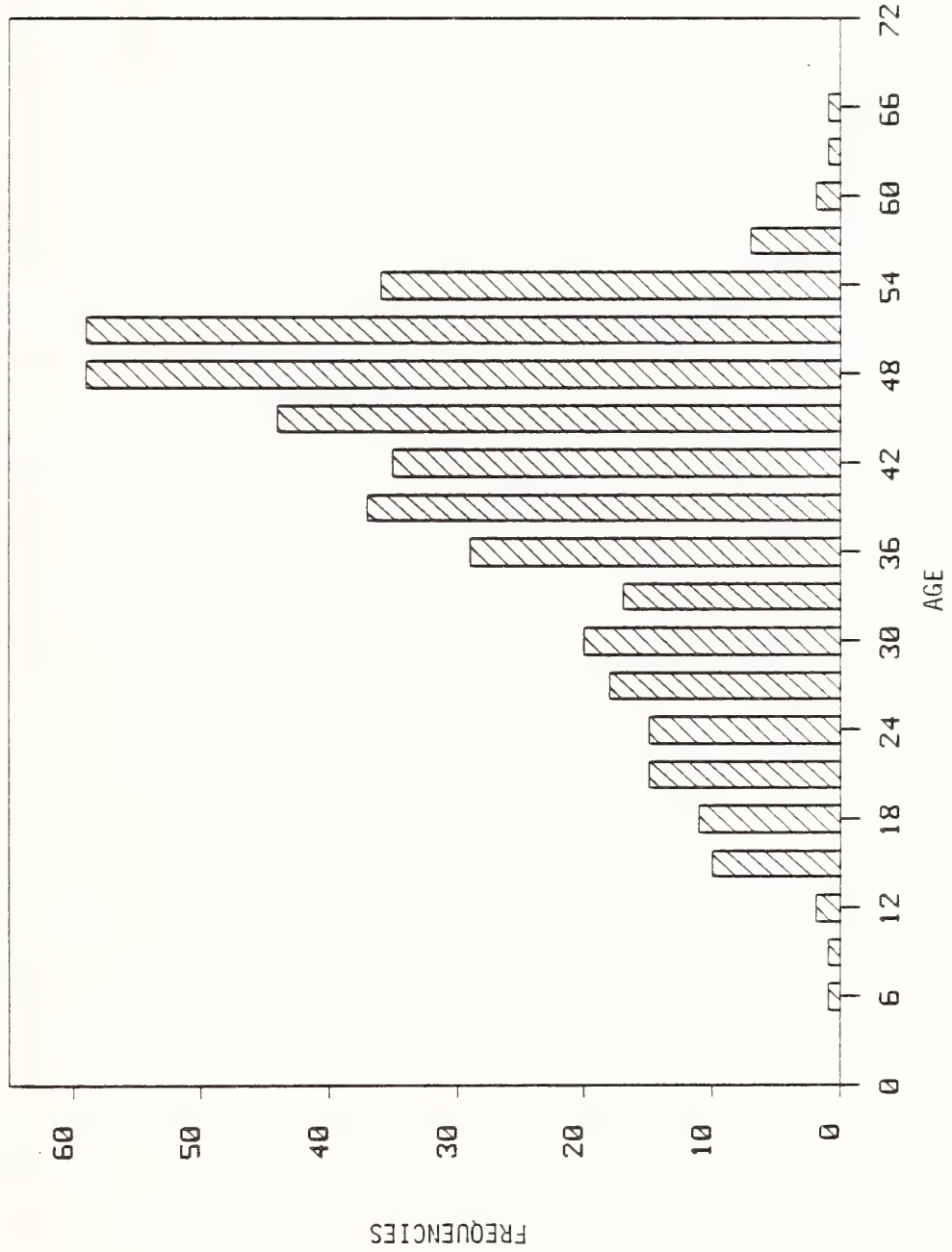


Figure 21-6
Year of Transplant

Figure 21-7
Age At Transplant



suddenly after age 54 (reflecting the age criterion imposed on heart transplant candidates).

As noted above, several other clinical and sociodemographic variables have been incorporated into the analysis of patient survival. Some of these variables have been discussed in Chapter 9. It is noteworthy that the majority (58.6%) of the patients in the study received their heart transplants at Stanford. The vast majority of patients are male (85.7 percent) and white (91.0 percent). The mean score on the Karnofsky Index of functional impairment for patients prior to transplantation is 7.52, reflecting a very low level of functional ability. Complete tables showing the frequencies for each of these, as well as other variables of interest, are provided in Appendix 21-E.

E. ESTIMATION PROCEDURES

Our efforts will concentrate on estimating or testing the following quantities:

(1) estimation of the hazard function, λ,

(2) exploration of the influence of covariates, i.e., testing the null hypothesis, H_0: $\beta=0$, and

(3) prediction of the survival rate at time t, $S(t) = \exp\left(-\int_0^t \lambda(s)ds\right)$ $(0 \leq t \leq 3942$ days).

Let T_i, $i=1, \ldots, n$, be independent, continuously distributed, positive random variables representing the times of death of n individuals, each of whom can only be observed for a fixed time interval. Data from a longitudinal study of n individuals can be represented concisely by the triple quantities (t_i, δ_i, Z_i),

where t_i is the observation time for the i th individual since his or her entry into the study, δ_i is a variable that indicates whether a transition into the state of death occurred at this time ($\delta_i=1$) or not ($\delta_i=0$), and Z_i is a vector of covariates. Suppose that individual i has hazard rate

$$\lambda_i(t) = \lim_{h \downarrow 0} \frac{1}{h} P\,[T_i \leq t+h \,|\, T_i \geq t]$$

with the multiplicative model

$$\lambda_i(t;\, \underline{Z}) = \lambda_0(t) \cdot \exp\,(\beta' Z_i(t)),$$

where β is a row vector of p unknown coefficients, Z_i is a column vector of p possibly time-dependent covariates, and λ_0 is a fixed unknown baseline hazard rate for an individual with $Z \equiv 0$.

Let the rate of transition into censorship, i.e., state of loss to follow-up by the termination of the study or some other reason, be represented in a separate risk function $\mu_i(t)$. Then, the probability density of the observation (t_i, δ_i) is given by:

$$f\,(t_i;\, \delta_i) = \lambda_i^{\delta_i}\,(t_i) \cdot \mu_i^{1-\delta_i}\,(t_i) \exp\,[-\int_0^{t_i} \left\{\lambda_i(s) + \mu_i(s)\right\} ds].$$

We assume that the death rate for the i th individual depends on his or her covariate information, Z_i and a vector, β of parameters (i.e., $\lambda_i(t) = \lambda(t; Z_i, \beta)$), whereas the competing risk, $\mu_i(t)$, is independent of the parameter vector, β. So, the full likelihood relevant to the parameter, β is, then:

$$L(\beta) = \prod_{i=1}^{n} \lambda^{\delta_i}\,(t_i;\, Z_i,\, \beta) \exp\left\{-\int_0^{t_i} \lambda_i(s) ds\right\}.$$

Cox (1972) further factorizes the full likelihood, $L(\beta)$, and utilizes the portion that is free from the nuisance function, $\lambda_o(t)$. Let

$$R(t) = \left\{ i: T_i \geq t \right\}$$

denote the risk set at time t, that is to say, the set of individuals i under observation at time t. Given R(t) and that at time t one individual in R(t) is observed to die, the probability that it is precisely individual i can be calculated as

$$\lambda(t; Z_i, \beta) \Big/ \sum_{j \in R(t)} \lambda(t; Z_j, \beta)$$

$$= \exp(\beta \cdot Z_i(t)) \Big/ \sum_{j \in R(t)} \exp(\beta \cdot Z_j(t));$$

a factor $\lambda_o(t)$ has cancelled out in numerator and denominator. Cox's factorization is based on the following intuitive argument: it seems reasonable that what is observed in the intervals of time between observed deaths does not contain any information on β, because λ_o is completely arbitrary. He therefore proposed that β can be inferred by considering

$$\text{partial } L(\beta) = \prod_{i:\delta_i=1} \exp(\beta . Z_i(t)) \Big/ \sum_{j \in R(t)} \exp(\beta . Z_j(t))$$

as a likelihood function.

Considerable discussion has occurred among statisticians regarding the nature and properties of the partial likelihood, particularly the possible applicability of standard maximum likelihood theory to it. Kalbfleisch and Prentice (1973) derived it as the marginal likelihood of the set of all possible rank order statistics consistent with the observed pattern of censorship. Breslow (1974) parametrized the

nuisance function λ_0 as a step function, taking on constant values between observed deaths, and derived L(ß) by the maximization of the full likelihood over λ_0 for fixed ß. Cox (1975) developed the theory of partial likelihood to show that such constructions, involving a certain chain of conditional probabilities, enjoyed large sample properties similar to those of ordinary likelihood functions. Despite these efforts, it is still not clear that standard large-sample maximum likelihood theory will lead to valid asymptotic results for inference on ß. Although promising, all of the work so far is very complicated and restricted in scope.

The decisive breakthrough occurred recently through the work of Andersen and Gill (1982), who showed how a firm mathematical basis can be given to the model in its fullest generality from which asymptotic properties can be derived in a completely natural way. They interpreted Cox's model as a multivariate intensity model where covariates have a proportional effect on the intensity of a multivariate counting process. The mathematical framework employs the multivariate counting process and stochastic integrals, and the large-sample theory is based on the martingale central limit theory. It was clearly shown that the maximum partial likelihood estimate of ß enjoys the standard asymptotic properties, and, hence, we can conduct hypothesis testing of ß=0 by using the Z-scores.

Denote the distinct failure times by

$$t_{(1)} < t_{(2)} < \ldots < t_{(k)}.$$

Let $m_{(i)}$ be the number of failure times equal to $t_{(i)}$, the multiplicity of course $\Sigma\, m_{(i)}=n$, and in the continuous case k=n,

$m_{(i)}=1$, theoretically (in practice, we may have multiplicity even in continuous case due to measurement error or precision). An estimator of the baseline cumulative hazard, $\Lambda_0(t) = \int_0^t \lambda_0(s)ds$ (Z=0), is

$$\hat{\Lambda}_0(t) = \sum_{t(j)\leq t} \frac{m_{(j)}}{r_{(j)}} ,$$

where $r_{(j)}$ = # of elements in the risk set, $R(t_{(j)})$.
An estimator for the baseline survival function is obtained analogously by

$$\hat{S}_0(t) = \prod_{t_{(j)}\leq t} (1 - \frac{m_{(j)}}{r_{(j)}}) .$$

Also, an estimator for the survival function of individuals with covariate, $Z_1(t)$ is

$$\hat{S}_1(t) = [\hat{S}_0(t)]^{\exp(\hat{\beta}.Z_1(t))} .$$

F. RESULTS

A total of 414 heart transplant recipients were included in this survival analysis. Of these, 242 received their heart transplants at Stanford while the remaining 172 were transplanted at one of the five other centers that participated in the National Heart Transplantation Study. A number of potential risk factors were incorporated into a Cox proportional hazards regression model to determine how they affected patient survival and to ascertain whether they increased the risk of mortality. These variables included sex, race, transplant

period, age at time of transplant, and level of functional impairment prior to transplant.

The first step in the analysis involved an extensive examination of the effect of sex on cardiac transplant recipient survival. Numerous other variables were included in the model although they were treated as nuisance factors. They were included in the Cox model only to insure that the estimate of the regression coefficient was rendered free of other confounding effects. Ultimately, no specific meaning is attached to the coefficients of these nuisance factors.

Determining what other variables should be controlled for in the regression analysis is not as straightforward as it would first appear. Generally, one would like to include all those variables that are a priori considered appropriate. According to Breslow (1980), even statistically non-significant variables should be included in the model, if inclusion of such variables changes the estimated coefficient of the variables of interest, in this case, patient sex, to any appreciable degree. If the model is saturated with the effects of all possible confounding factors, the estimated coefficient of the variable (sex) is said to reach equilibrium. As shown in Table 21-3, the estimated coefficients associated with sex changed dramatically from Model 1 to Model 3, although none of these coefficients are statistically significant. After the third model, the estimates reached a state of equilibrium. Based on this, it is reasonable to conclude that an unbiased estimate of the effect of sex is approximately 0.265 with a Z score of 1.35 or 1.38.

Table 21-3
Results of Fitting Cox Regression Models: All Heart Transplant Patients
(N = 414)

Model	1	2	3	4	5[b]	6[b]	7[b]	8[b]
Number of Parameter	2	3	6	7	2	5	5	6
Log Likelihood	-1263.55	-1262.86	-1246.18	-1246.10	-1167.97	1151.55	-1151.64	-1151.39
Sex	0.038 (0.202)[a]	0.037 (0.195)	0.261 (1.35)	0.266 (1.38)				
Race		0.291 (1.123)	0.181 (0.696)	0.191 (0.735)	0.289 (1.112)	0.173 (0.663)		0.182 (0.697)
Year of Transplant			-0.044 (-2.63)			-0.044 (-2.64)		
Transplant Period: 1968-1973								
Transplant Period: 1974-1979				-0.382 (-2.15)			-0.391 (-2.18)	-0.388 (-2.17)
Transplant Period: 1980-1983				-0.486 (-2.66)			-0.491 (-2.68)	-0.489 (-2.67)
Age at Transplant			0.021 (3.08)	0.022 (3.24)		0.021 (3.06)	0.022 (3.21)	0.022 (3.14)
Functional Impairment Just Before Transplant			0.148 (3.21)	0.151 (3.27)		0.147 (3.16)	0.151 (3.25)	0.150 (3.23)

[a] b/s.e.(b)

[b] Stratified Cox model by sex.

$\lambda_1(t; \underline{Z}) = \lambda_{01}(t) \cdot \exp(\underline{\beta} \cdot \underline{Z})$; male

$\lambda_2(t; \underline{Z}) = \lambda_{02}(t) \cdot \exp(\underline{\beta} \cdot \underline{Z})$; female

Precision in the estimation process is lost when extraneous or nonessential variables are included in a model. Such extraneous variables have either non-significant coefficients or coefficients whose magnitude is smaller than the standard deviation of the estimate. At this point in the analysis, however, the primary concern is not to achieve precision in the estimation process, but rather to control the potential confounding effects of the nuisance factors.

In a similar fashion, the effects of other variables such as race, transplant period, and so forth can be taken into consideration. As shown in Table 21-3, a comparison of the maximized log-likelihood between the second and third models reveals that an improved fit of the data with the model corresponds to the inclusion of three additional variables, namely, transplant period, age at transplant, and functional impairment just before transplant.

$$[X_3^2 = 2(1262.86 - 1246.18) = 33.36,\ p < 0.0001].$$

The third and fourth models fit equally well, as their log likelihoods are -1246.18 and -1246.10, respectively. In the fourth model, an additional variable--transplant period--has been included. Three specific time periods have been identified in an attempt to ascertain the extent to which improvements in cardiac transplant technology might contribute to a better fit of the Cox model.

The subsequent models in Table 21-3 are stratified by sex, the immediate effect of which is to make the incidence ratio of mortality of individuals characterized by explanatory variablex $\underline{Z}$, and $\underline{Z}_0$ at post-transplant time t proportional with sex. In other words, the

regression coefficient, β, is invariant for both sexes and, hence, so is the relative risk for a given pair of covariates.

As revealed in Table 21-3, stratification improved the overall fit of the models when they are compared with their corresponding non-stratified models, yet the regression coefficients themselves changed very little. This can be seen, for example, by comparing Model 3 with Model 6 and Model 4 with Model 8.

It is instructive to examine the Stanford data independent of that of other transplant centers. The results of these analyses are shown in Table 21-4. As can be seen, the overall results are very similar to those presented in Table 21-3. Survival improved with transplant period, while both age at transplant and functional impairment prior to transplant are statistically significant. Neither race nor sex have a significant effect.

Cox regression coefficients for Model 4 contained in Table 21-3, are presented in Table 21-5, along with the 95 percent confidence limits for each variable. Variables are significant at the .05 level if the confidence interval does not contain zero. As can be seen from Table 21-5, year of transplant, age at transplant, and functional ability prior to transplant are all statistically significant. Race and sex, however, are not statistically significant.

Based on the regression coefficients reported in Table 21-5, it is possible to compute the risk of death, as a function of time after transplantation, and to determine the influence of covariates (such as age and sex) on this risk. Table 21-6 summarizes the relative risk of mortality after heart transplantation in relation to various risk

Table 21-4
Results of Fitting Cox Regression Models: Stanford Patients Only
(N = 242)

Model	1	2	3	4	5[b]	6[b]	7[b]
Number of Parameter	2	3	6	7	2	5	6
Log Likelihood	-714.26	-713.33	-692.20	-691.89	-658.90	-637.52	-637.27
Sex	-0.059 (0.236)[a]	-0.073 (0.290)	0.237 (0.91)	0.274 (1.05)			
Race		0.463 (1.272)	0.279 (0.759)	0.291 (0.790)	0.455 (1.25)	0.258 (0.701)	0.267 (0.724)
Year of Transplant			-0.077 (-3.51)			-0.078 (3.52)	
Transplant Period: 1968-1973				-0.457 (-2.34)			-0.480 (2.46)
Transplant Period: 1974-1979				-0.898 (-3.467)			-0.892 (-3.44)
Transplant Period: 1980-1983							
Age at Transplant			0.022 (2.41)	0.024 (2.60)		0.023 (2.45)	0.024 (3.22)
Functional Impairment Just Before Transplant			0.205 (3.02)	0.218 (3.20)		0.208 (3.06)	0.221 (3.22)

[a] b/s.e.(b)

[b] Stratified Cox model by sex.

$$\lambda_1(t; \underline{Z}) = \lambda_{01}(t) \cdot \exp(\underline{\beta} \cdot \underline{Z}); \text{ male}$$

$$\lambda_2(t; \underline{Z}) = \lambda_{02}(t) \cdot \exp(\underline{\beta} \cdot \underline{Z}); \text{ female}$$

Table 21-5
Estimates of the Cox Regression Coefficients
Based on the Fourth Model

BETA	ESTIMATES	STD.DEV.	LOWER[b]	UPPER
Sex	.2659	.1931	-.1126	.6444
Race	.1910	.2603	-.3191	.7011
Transplant Period[a]				
Year 2	-.3816	.1783	-.7312	-.0321
Year 3	-.4861	.1832	-.8452	-.1271
Age at Transplant	.0218	.0069	.0082	.0333
Functional Impairment	.1513	.0462	.0607	.2419

[a]Year of Heart Transplant = 1968-1973, if Year 2 = 0, Year 3 = 0, 1974-1979, if Year 2 = 1, Year 3 = 0, and 1980-1983, if Year 2 = 0, Year 3 = 1.

[b]95% Confidence Limits.

Table 21-6
Relative Risks of Mortality After Heart Transplant in Relation to Various Potential Risk Factors: Results of Proportional Hazards Analyses Controlling For The Other Risk Factors

Risk Factors	Number of Recipients Dead	Alive	Relative Risk	95%CI	$X^2_{(1)}$	p-Value
Sex						
- Male	208	152	1.00			
- Female	34	26	1.30	0.896-1.904	1.90	1.25
Race						
- Nonwhite	15	20	1.00			
- White	224	158	1.21	0.727-2.016	0.54	0.25
Transplant Period						
1968-1973	58	5	1.00 (1.61)			
1974-1979	89	41	0.68 (1.47)	0.484-0.969	4.62	0.05
1980-1983	95	132	0.62 (1.00)	0.730-0.881	7.08	0.01
Age at Transplant*					10.50[a]	0.001
-20	17	20	1.00			
20 - 30	23	33	1.25			
30 - 40	48	47	1.55			
40 - 50	103	65	1.93			
50+	51	13	2.41			
Functional Impairment					10.69[a]	0.001
1	0	1	1.00			
4	5	8	1.57			
5	14	12	1.82			
6	29	26	2.13			
7	69	62	2.88			
8	38	15	3.35			
9	64	35	3.35			
10	22	17	3.89			

*Based on a restrictive proportional hazards model.

[a]Score test for linear trend.

factors included in the proportional hazards analyses, controlling for all other risk factors included in the regression equation. Thus, since all the relative risks are adjusted for each other, they can be interpreted independently.

For example, it is possible to compute the relative risk of death for males compared with females. Based on the Cox regression equation coefficient estimates reported in Table 21-5, the estimated coefficient of the sex variable is .2659. Thus, the relative risk of death for females is given by exp(.2659(1-0)) = 1.30, compared with a relative risk of 1.0 for males. In a similar manner, 95 percent confidence limits of the relative risk are obtained by using the lower and upper estimates of the regression coefficients (as reported in Table 21-5).

The relative risks, as shown in Table 21-6, indicate that the risk of death for females is 1.3 times greater than for males, while the risk for whites is 1.2 times that for nonwhites. However, with chi-square statistics of 1.90 and 0.54 respectively, neither difference is statistically significant.

With respect to the other risk factors (transplant period, age at transplant and functional impairment), some interesting differences can be observed. The relative risks of mortality associated with transplant period clearly show a decreasing risk associated with more recent transplants. Compared with a risk of 1.0 for the baseline period (1968-1973), the relative risk is only .68 for the period 1974-1979 and .62 for the period 1980-1983. The chi-square statistics (4.62 and 7.08, respectively) show that these differences are highly

significant, confirming the fact that transplantation technology has improved and, therefore, survival rates have indeed increased in more recent years.

Finally, a comparison of relative risks shows that those patients with less functional impairment prior to transplantation have a lower risk of death following transplantation. Table 21-6 shows that those patients who were reported to have a Karnofsky Index of 10 (moribund, fatal processes progressing rapidly) have a relative risk of death which is almost 4 times as great as those who are in good health. Indeed, it is clear that the relative risk of death increases steadily as the condition of the patient deteriorates. These statistically significant differences in the relative risks of mortality after transplantation with respect to both functional impairment and age at transplant, provide strong support for the use of patient selection criteria in allocating a limited supply of donor organs among a pool of heart transplant candidates.

Based on the Cox regression models presented in Table 21-3, we then computed expected survival curves for various patient groups. Figure 21-8 presents expected survival curves for whites and nonwhites, Figure 21-9 presents similar curves for males and females, and Figure 21-10 presents survival curves for the three transplant periods. Figures 21-8 and Figure 21-10 were constructed using Model 4 in Table 21-3, while Figure 21-9 was constructed using Model 8. Estimated life tables for the various patient groups are presented in Appendices 21-F through 21-K.

In interpreting the survival curves, the horizontal axis represents time since transplantation (in days), and the vertical axis indicates

Figure 21-8
Expected Survival Curves of Heart Transplant Recipients, By Race

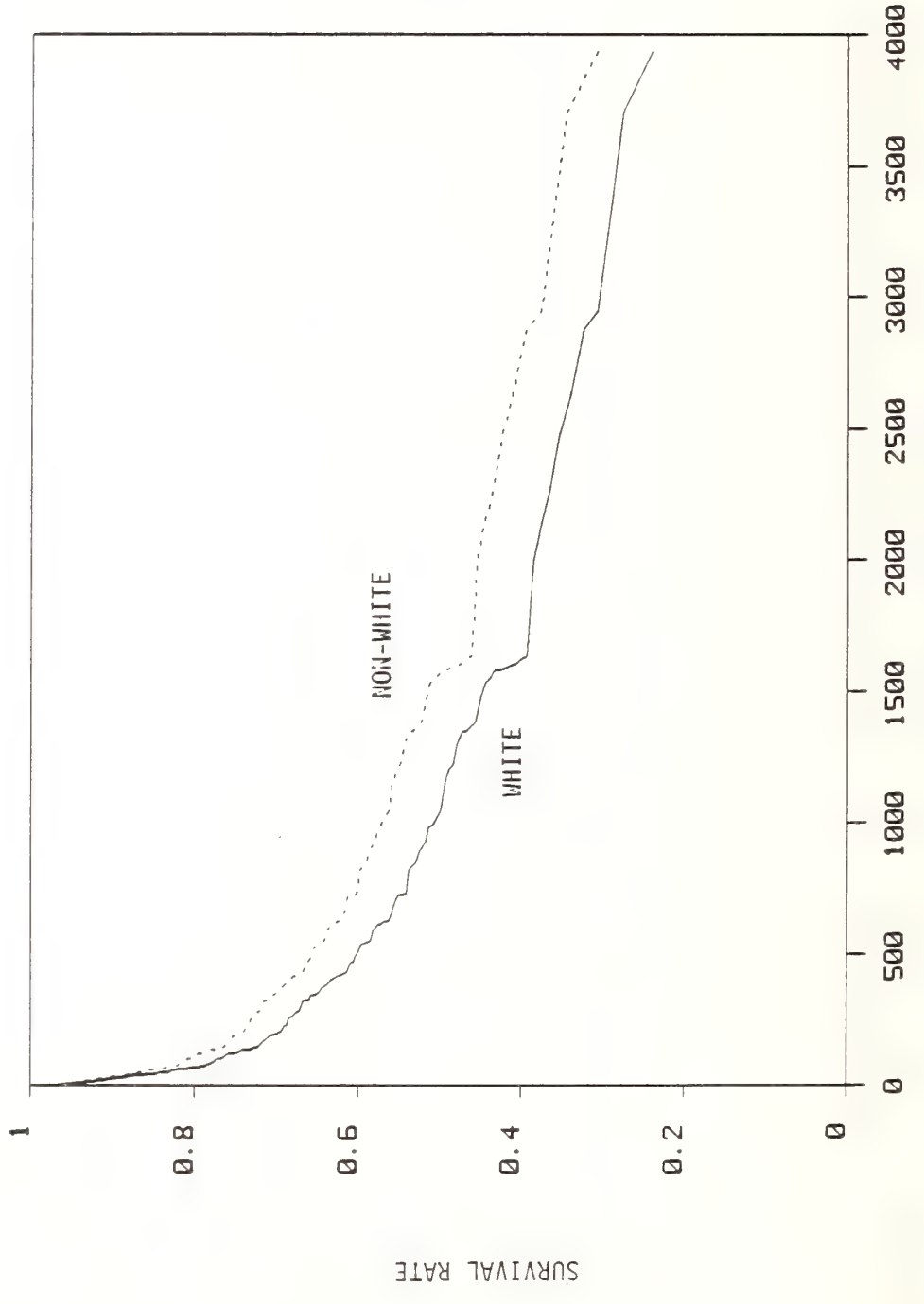


Figure 21-9
Expected Survival Curves of Heart Transplant Recipients, By Sex

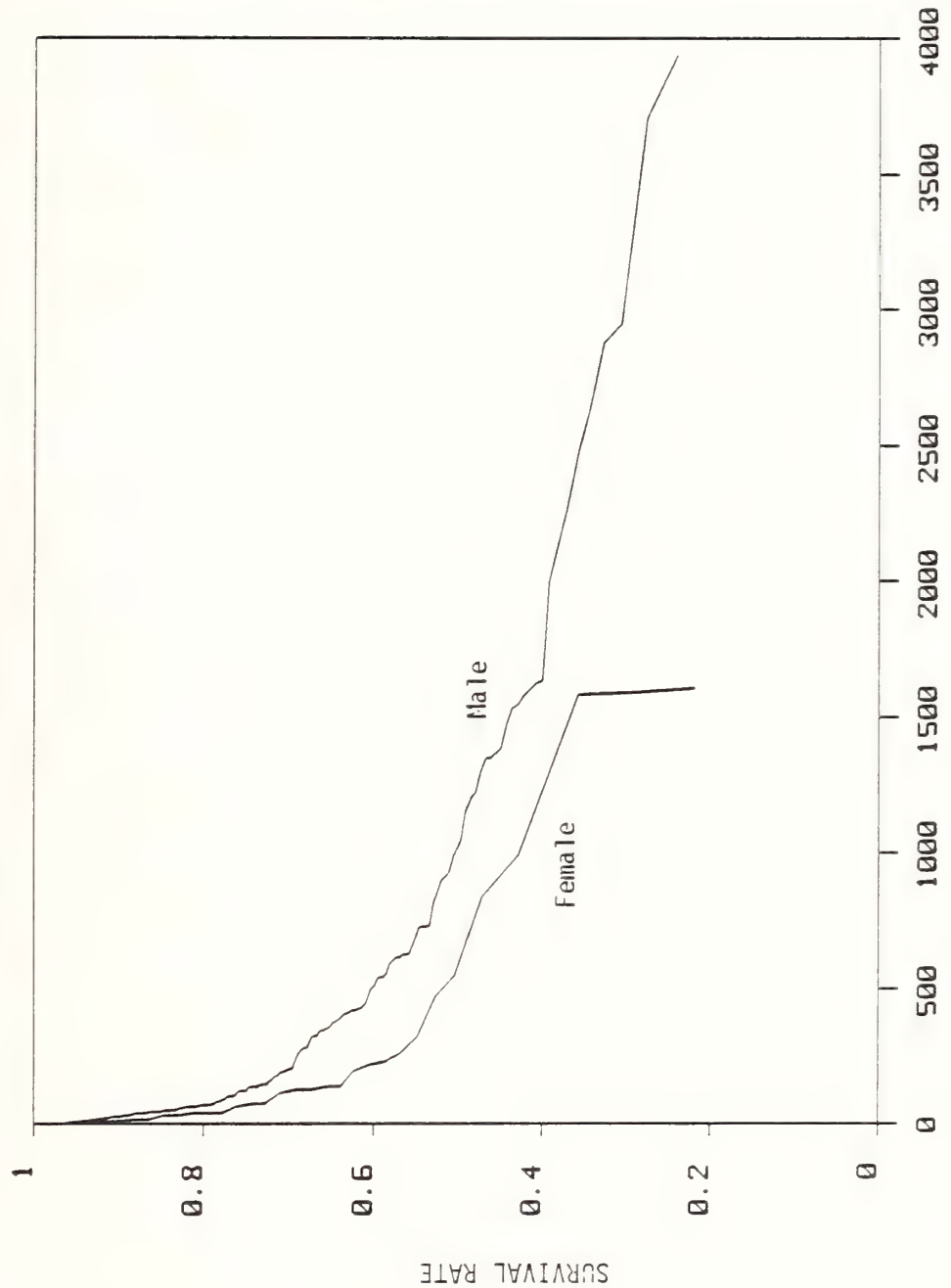
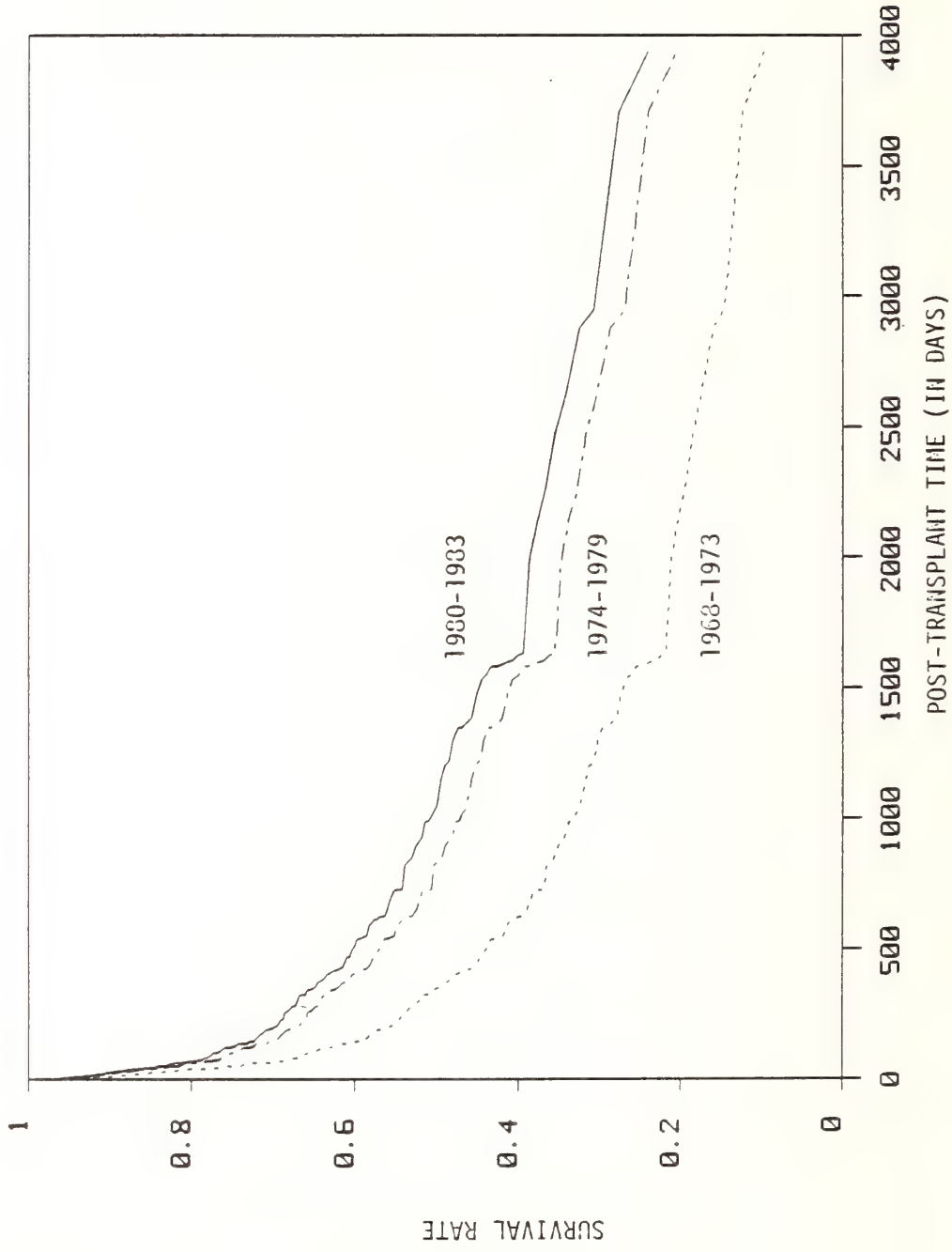


Figure 21-10
Expected Survival Curves of Heart Transplant Recipients
By Transplant Period



the estimated survival rates (i.e., the proportion surviving). The median survival time for whites is approximately 1000 days (2.7 years), compared with 1600 days for nonwhites (see Figure 21-8). For males, the median survival time is approximately 1000 days, compared with 600 days for females. Because few females have received heart transplants, estimates of survival were not made beyond 1600 days (thus, in Figure 21-9 the survival curve for females is truncated at this point). Moreover, it should be recognized that the estimates of survival for females are much less reliable near the end of the curve.

The survival curves clearly demonstrate that the first 500 days following transplantation constitute a relatively high risk period, with the mortality rate stabilizing after this time. The survival curves show that over 60 percent of heart transplant recipients do live beyond the first 500 days, and in fact, one-quarter of the recipients can be expected to survive over 10 years. In addition, as Figure 21-10 shows, survival rates have improved considerably in recent years. This improvement is most noticeable in terms of the estimated long-term survival of transplant recipients.

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APPENDIX 21-A

POSSIBLE COVARIATES FOR THE HEART TRANSPLANT RECIPIENT SURVIVAL ANALYSIS

Question No.	Variable	Value Codes
0	Transplant Center	1-5 = Non-Stanford 6 = Stanford
0	Transplant Status	1 = Recipient 2 = Nonrecipient
9	Sex	1 = Male 2 = Female
10	Race	4 = White 1, 2, 3, 5, 6 = Others -2 = DK
18	Karnofsky Index at Time of Evaluation	
37	Date of Candidacy Decision	mm/dd/yy
55	Karnofsky Index just before Transplant	
51, 52	Number of Heart Transplants	1-5
70	Immunosuppressive Drugs After Surgery	70.8 = Cyclosporine 70.1-70.7, 70.9-70.10 = Other
77	Date of Transplant	mm/dd/yy
88	Patient Living or Deceased	1 = Living 2 = Deceased
91	Date of Death	mm/dd/yy

Created Covariates For Survival Analysis

Age at Candidacy	Years
Age at Transplant	Years

APPENDIX 21-B

SURVIVAL ANALYSIS: POSSIBLE GROUPINGS

YEAR OF TRANSPLANT (Q.77)

YEAR OF CANDIDACY (Q.37)

(1)	(2)	(3)
No Grouping	'68 - '73 '74 - '83	'68 - '73 '74 - '79 '80 - '83

AGE AT TRANSPLANT

AGE AT CANDIDACY

(1)	(2)	(3)
No Grouping	6-18 19-30 43-54 55-66	6-20 21-30 41-50 51-60 61-

CENTER (Q.0)

(1)	(2)	(3)
1-6 (Aggregated)	1-5 (Non-Stanford) 6 (Stanford)	1 2 3 4 5 6

RACE (Q.10)

4	White
1-3	Non-White

DIAGNOSIS (Q.18)

(1)	
2	Idiopathic Cardiomyopathy
3	Valve disease with CM
1, 4-8	Other

KARNOFSKY INDEX AT TIME OF TRANSPLANT (Q.55)

(1)
1-4
5
6
7
8
9
10

HLA MATRCHES (Q.57)

(1)	(2)	(3)
0	0	0
1-6	1	1
	2-6	2
		3-6

APPENDIX 21-C

SUMMARY OF MISSING DATA

I.D. No.	RACE	DIAGNOSIS	KARNOFSKY[a] INDEX	CYCLOSPORINE	HLA[b] MATCHES
611084	MIS	2	7	1	0
612026	MIS	1	9	2	3
612039	MIS	2	8	2	1
311008	4	MIS	MIS	MIS	MIS
511009	4	MIS	6	1	3
611028	4	MIS	7	2	0
611080	4	MIS	MIS	MIS	MIS
612028	4	MIS	6	2	1
312018	4	2	MIS	2	MIS
111003	2	2	5	MIS	1
611016	4	1	9	MIS	0

[a]Karnofsky Index just prior to transplant.

[b]51 Other cases have missing code for HLA matches.
Code 77 represents test not performed (NP) and is treated as missing.

N = 420

No.	Model	Sample Size
1	+ RACE	N - 3
2	+ RACE + KARI	N - 6
3	+ RACE + KARI + DIAG + CYCL	N - 11
4	+ RACE + KARI + DIAG + CYCL + HLA	N - 62

NOTE: KARI = Karnofsky Indez; DIAG = Diagnosis; CYCL = Cyclosporine; HLA = HLA Matches.

APPENDIX 21-D

HISTOGRAMS OF TIME VARIABLES

Figure 21-D-1
Waiting Time Of Heart Transplant Recipients

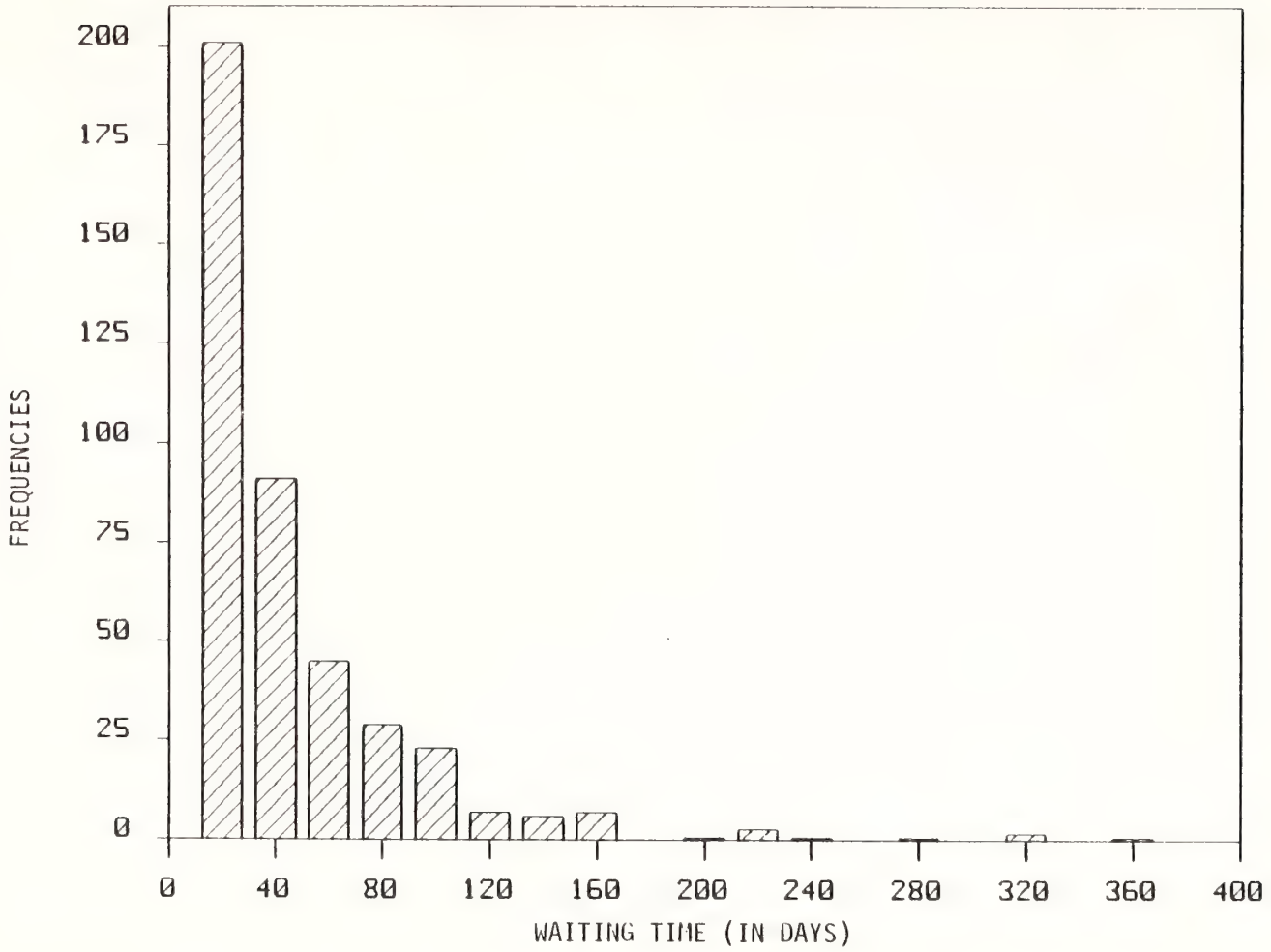


Figure 21-D-2
Year of Candidacy of Heart Transplant Recipients

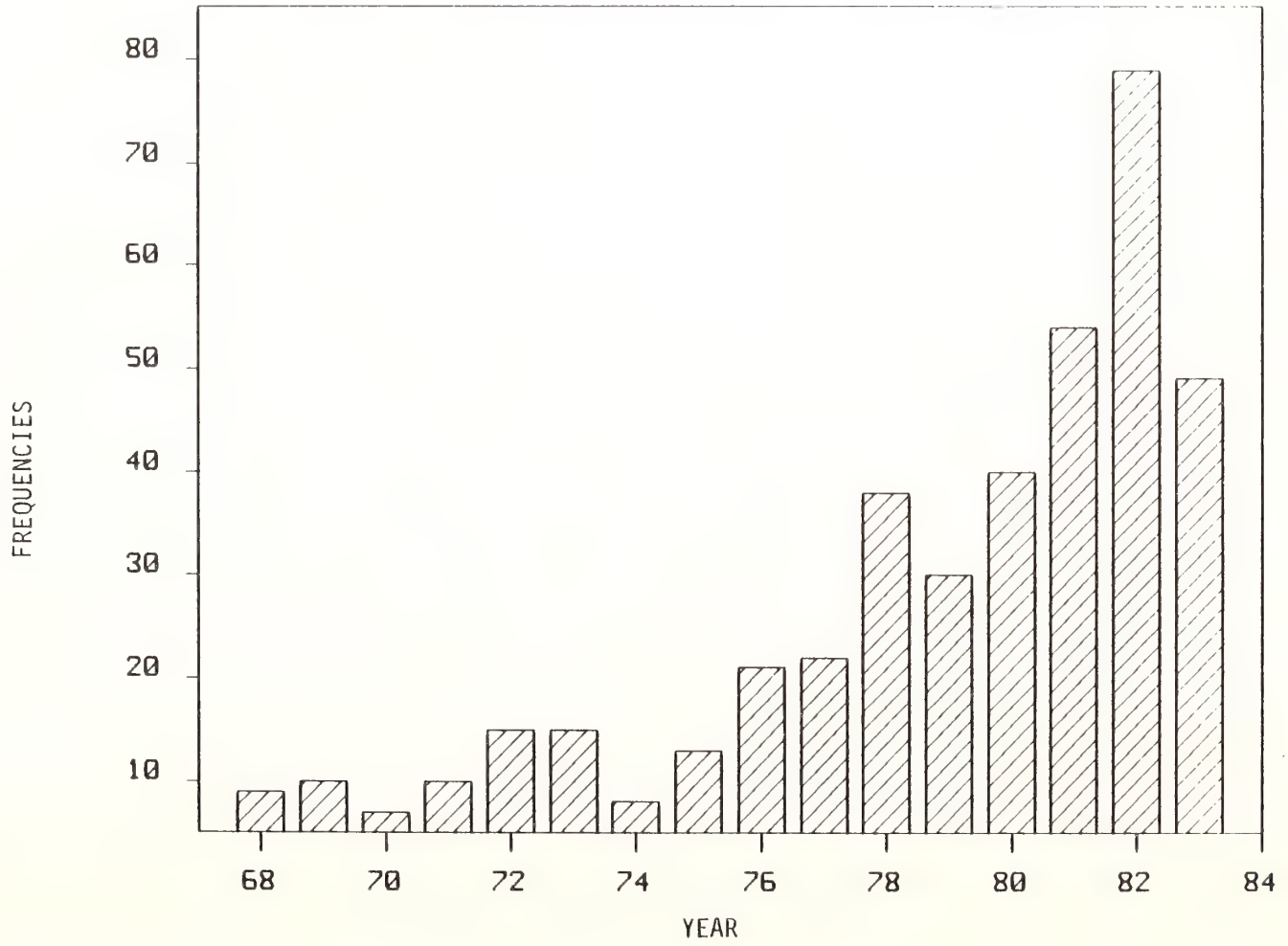
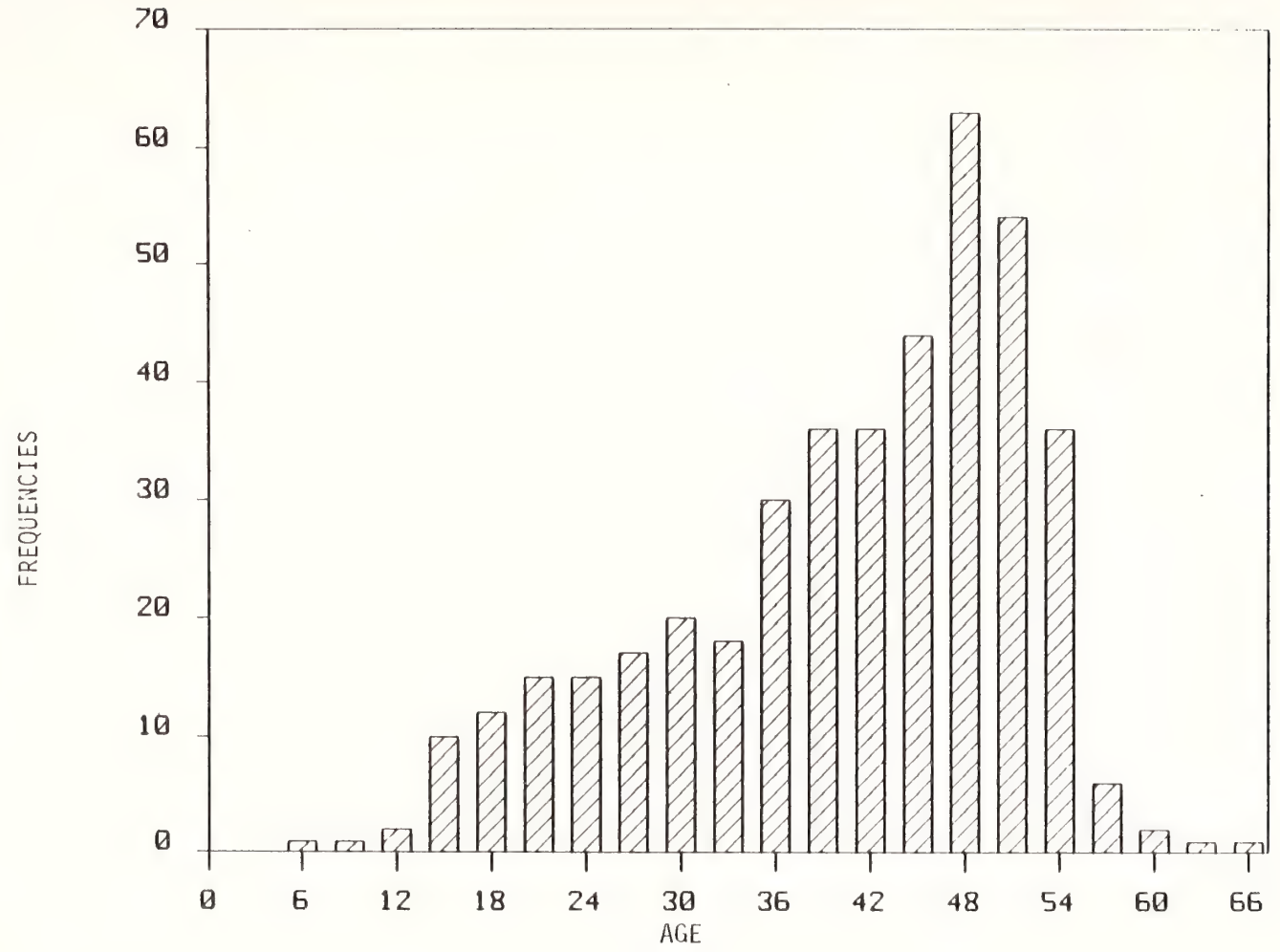


Figure 21-D-3
Age At Candidacy For Heart Transplant Recipients



APPENDIX 21-E

FREQUENCIES OF SOCIODEMOGRAPHIC AND CLINICAL VARIABLES OF INTEREST FOR THE SURVIVAL ANALYSIS

Table 21-E-1
Number of Heart Transplant Recipients By Center

CENTER	NUMBER	PERCENT
ARIZONA	39	9.3
COLUMBIA	29	6.9
MCV	37	8.8
MINNESOTA	20	4.8
PITTSBURGH	49	11.7
STANFORD	246	58.6

Valid Cases = 420

Table 21-E-2
Number of Heart Transplant Recipients By Sex

	NUMBER	PERCENT
MALE	360	85.7
FEMALE	60	14.3

Valid Cases = 420

Table 21-E-3
Number of Heart Transplant Recipients By Race

RACE	NUMBER	PERCENT
Black	17	4.0
Chicano	6	1.4
White	382	91.0
Oriental	8	1.9
Other	4	1.0
Missing	3	.7

Valid Cases = 417

Table 21-E-4
Primary Diagnosis of Heart Transplant Recipients

DIAGNOSIS	NUMBER	PERCENT
Coronary Artery Disease	184	43.8
Idiopathic Cardiomyopathy (CM)	198	47.1
Valve Disease With CM	6	1.4
Rheumatic Valvular Disease	12	2.9
Other	15	3.5
Missing	5	1.2

Valid Cases = 415

Table 21-E-5
Functional Impairment of Heart Transplant Recipients
Just Before Transplantation (Karnofsky Index)

INDEX CATEGORY	NUMBER	PERCENT
Normal; No Complaints; No Evidence of Disease	1	.2
Care For Self; Unable to Carry on Normal Activity or do Active Work	13	3.1
Requires Occasional Assistance But is Able to Care For Most of Own Needs	26	6.2
Requires Considerable Assistance and Frequent Medical Care	55	13.1
Disabled; Requires Special Care and Assistance	131	31.2
Severely Disabled; Hospitalization is Indicated Although Death Not Imminent	53	12.6
Very Sick; Hospitalization Necessary	99	23.6
Moribund; Fatal Processes Progressing Rapidly	39	9.3
Missing	3	.7

Valid Cases = 417

Table 21-E-6
Number of HLA Matches

NUMBER OF ANTIGAN MATCHES	NUMBER	PERCENT
0	129	30.7
1	150	35.7
2	54	12.9
3	19	4.5
4	2	.5
5	3	.7
6	3	.7
Missing	60	14.3

Valid Cases = 360

Table 21-E-7
Immunosuppressive Drugs Prescribed

	NUMBER	PERCENT
Cyclosporine	126	30.0
Other	289	68.8
Missing	5	1.2

Valid Cases = 415

Table 21-E-8
Status of Heart Transplant Recipient
At Time of Survey

	NUMBER	PERCENT
Living	178	42.4
Deceased	242	57.6

Valid Cases = 420

APPENDIX 21-F

ESTIMATED LIFE TABLE FOR WHITE HEART TRANSPLANT RECIPIENTS

NUMBER AT RISK	NUMBER FAILING	TIME	EST. SURV PROB	EST. HAZ RATE
409	10.	1.000	.9803	.1990E-01
399	5.	2.000	.9703	.1021E-01
394	2.	3.000	.9663	.4131E-02
392	5.	7.000	.9563	.1039E-01
387	1.	8.000	.9543	.2102E-02
386	3.	9.000	.9483	.6325E-02
383	2.	10.000	.9442	.4248E-02
381	2.	11.000	.9402	.4279E-02
379	1.	12.000	.9382	.2153E-02
378	1.	13.000	.9362	.2160E-02
377	1.	14.000	.9341	.2166E-02
376	2.	15.000	.9301	.4344E-02
374	3.	17.000	.9240	.6580E-02
371	3.	21.000	.9179	.6636E-02
368	2.	22.000	.9138	.4453E-02
366	1.	23.000	.9117	.2249E-02
365	3.	25.000	.9056	.6761E-02
362	1.	26.000	.9035	.2284E-02
361	1.	27.000	.9014	.2294E-02
360	1.	28.000	.8994	.2298E-02
359	3.	29.000	.8932	.6907E-02
356	1.	30.000	.8911	.2327E-02
355	2.	31.000	.8870	.4665E-02
353	2.	36.000	.8828	.4683E-02
351	3.	39.000	.8766	.7061E-02
348	2.	40.000	.8724	.4769E-02
346	1.	41.000	.8703	.2398E-02
345	2.	42.000	.8662	.4814E-02
343	2.	43.000	.8620	.4838E-02
341	1.	44.000	.8599	.2439E-02
340	1.	45.000	.8578	.2447E-02
339	1.	46.000	.8557	.2455E-02
338	2.	47.000	.8515	.4928E-02
336	2.	48.000	.8472	.4982E-02
334	1.	49.000	.8451	.2511E-02
333	2.	50.000	.8408	.5040E-02
331	3.	51.000	.8345	.7609E-02
328	1.	53.000	.8323	.2579E-02
327	1.	54.000	.8302	.2590E-02
326	1.	60.000	.8280	.2600E-02
325	1.	62.000	.8258	.2615E-02
324	2.	63.000	.8215	.5244E-02
322	1.	64.000	.8193	.2658E-02
321	2.	65.000	.8150	.5347E-02
319	1.	66.000	.8128	.2706E-02
318	1.	67.000	.8106	.2711E-02
317	3.	68.000	.8040	.8146E-02
314	2.	70.000	.7996	.5493E-02
312	2.	72.000	.7952	.5515E-02
310	1.	73.000	.7930	.2779E-02
309	1.	74.000	.7908	.2790E-02
308	1.	76.000	.7886	.2797E-02

307	2.	85.000	.7841	.5619E-02
305	1.	86.000	.7819	.2822E-02
304	1.	89.000	.7797	.2827E-02
303	1.	90.000	.7775	.2836E-02
302	1.	100.000	.7753	.2844E-02
301	1.	102.000	.7731	.2857E-02
300	1.	105.000	.7709	.2867E-02
299	1.	106.000	.7687	.2874E-02
298	1.	108.000	.7664	.2888E-02
297	1.	114.000	.7642	.2898E-02
296	1.	118.000	.7620	.2902E-02
295	1.	121.000	.7598	.2911E-02
294	3.	122.000	.7532	.8761E-02
291	1.	127.000	.7509	.2957E-02
290	1.	128.000	.7487	.2985E-02
289	2.	136.000	.7442	.5989E-02
287	2.	137.000	.7397	.6069E-02
285	2.	138.000	.7352	.6115E-02
283	1.	139.000	.7329	.3080E-02
282	1.	145.000	.7307	.3092E-02
281	2.	146.000	.7262	.6200E-02
279	1.	147.000	.7239	.3124E-02
277	1.	158.000	.7216	.3153E-02
276	1.	161.000	.7193	.3164E-02
274	1.	171.000	.7170	.3195E-02
273	1.	174.000	.7147	.3208E-02
270	1.	181.000	.7124	.3234E-02
268	1.	189.000	.7101	.3260E-02
267	1.	191.000	.7078	.3269E-02
266	2.	198.000	.7032	.6563E-02
264	1.	202.000	.7008	.3313E-02
263	1.	204.000	.6985	.3326E-02
262	1.	205.000	.6962	.3340E-02
259	1.	221.000	.6938	.3378E-02
258	1.	228.000	.6915	.3388E-02
256	1.	231.000	.6891	.3409E-02
249	1.	253.000	.6867	.3505E-02
246	1.	263.000	.6843	.3540E-02
245	1.	265.000	.6819	.3561E-02
243	1.	275.000	.6794	.3589E-02
242	1.	281.000	.6770	.3601E-02
240	1.	282.000	.6745	.3656E-02
235	1.	293.000	.6720	.3744E-02
226	1.	322.000	.6694	.3888E-02
225	1.	325.000	.6668	.3920E-02
224	1.	327.000	.6641	.3929E-02
223	1.	328.000	.6615	.3941E-02
220	1.	344.000	.6589	.3976E-02
219	1.	347.000	.6563	.3989E-02
217	1.	350.000	.6536	.4023E-02
216	2.	362.000	.6484	.8063E-02
211	1.	373.000	.6457	.4139E-02
209	2.	382.000	.6403	.8343E-02
207	1.	387.000	.6376	.4210E-02
204	1.	402.000	.6349	.4249E-02
203	1.	409.000	.6322	.4273E-02
202	1.	414.000	.6295	.4287E-02
200	1.	416.000	.6268	.4336E-02
199	2.	425.000	.6214	.8716E-02
197	1.	426.000	.6186	.4402E-02

193	1.	431.000	.6159	.4482E-02
191	1.	442.000	.6131	.4557E-02
183	1.	471.000	.6101	.4761E-02
182	1.	473.000	.6072	.4783E-02
177	1.	497.000	.6043	.4920E-02
174	1.	513.000	.6012	.5011E-02
172	1.	537.000	.5982	.5056E-02
170	2.	543.000	.5921	.1024E-01
168	1.	547.000	.5890	.5208E-02
167	1.	551.000	.5859	.5263E-02
159	1.	592.000	.5827	.5493E-02
156	1.	600.000	.5795	.5598E-02
154	1.	615.000	.5762	.5652E-02
153	1.	617.000	.5729	.5679E-02
152	1.	624.000	.5697	.5696E-02
151	1.	628.000	.5664	.5759E-02
149	1.	632.000	.5631	.5835E-02
145	1.	655.000	.5597	.5977E-02
140	1.	695.000	.5563	.6149E-02
135	1.	728.000	.5528	.6328E-02
134	3.	730.000	.5423	.1917E-01
120	1.	826.000	.5384	.7223E-02
119	1.	836.000	.5345	.7300E-02
118	1.	850.000	.5305	.7416E-02
115	1.	897.000	.5265	.7596E-02
112	1.	912.000	.5224	.7823E-02
110	1.	929.000	.5182	.7976E-02
104	1.	986.000	.5139	.8377E-02
100	1.	994.000	.5095	.8614E-02
96	1.	1024.000	.5049	.9071E-02
94	1.	1051.000	.5002	.9409E-02
88	1.	1150.000	.4953	.9851E-02
85	1.	1203.000	.4903	.1012E-01
82	1.	1218.000	.4852	.1043E-01
78	1.	1301.000	.4799	.1091E-01
74	1.	1350.000	.4745	.1141E-01
73	1.	1352.000	.4689	.1172E-01
71	2.	1384.000	.4576	.2442E-01
66	1.	1478.000	.4517	.1303E-01
62	1.	1535.000	.4455	.1375E-01
60	1.	1548.000	.4392	.1415E-01
58	1.	1582.000	.4329	.1448E-01
57	1.	1583.000	.4265	.1475E-01
56	1.	1592.000	.4202	.1497E-01
54	1.	1601.000	.4137	.1545E-01
53	1.	1605.000	.4072	.1589E-01
51	1.	1627.000	.4005	.1654E-01
49	1.	1634.000	.3937	.1708E-01
43	1.	1996.000	.3862	.1929E-01
33	1.	2143.000	.3768	.2460E-01
29	1.	2268.000	.3666	.2735E-01
26	1.	2475.000	.3555	.3060E-01
22	1.	2627.000	.3428	.3634E-01
16	1.	2878.000	.3259	.5032E-01
15	1.	2949.000	.3080	.5622E-01
7	1.	3707.000	.2779	.1018
5	1.	3942.000	.2409	.1411

APPENDIX 21-G

ESTIMATED LIFE TABLE FOR NON-WHITE HEART TRANSPLANT RECIPIENTS

NUMBER AT RISK	NUMBER FAILING	TIME	EST. SURV PROB	EST. HAZ RATE
409	10.	1.000	.9837	.1644E-01
399	5.	2.000	.9754	.8438E-02
394	2.	3.000	.9721	.3413E-02
392	5.	7.000	.9638	.8581E-02
387	1.	8.000	.9621	.1736E-02
386	3.	9.000	.9571	.5225E-02
383	2.	10.000	.9537	.3509E-02
381	2.	11.000	.9503	.3535E-02
379	1.	12.000	.9487	.1778E-02
378	1.	13.000	.9470	.1784E-02
377	1.	14.000	.9453	.1790E-02
376	2.	15.000	.9419	.3589E-02
374	3.	17.000	.9368	.5436E-02
371	3.	21.000	.9316	.5482E-02
368	2.	22.000	.9282	.3679E-02
366	1.	23.000	.9265	.1858E-02
365	3.	25.000	.9213	.5585E-02
362	1.	26.000	.9196	.1887E-02
361	1.	27.000	.9179	.1895E-02
360	1.	28.000	.9161	.1899E-02
359	3.	29.000	.9109	.5706E-02
356	1.	30.000	.9092	.1922E-02
355	2.	31.000	.9057	.3854E-02
353	2.	36.000	.9022	.3869E-02
351	3.	39.000	.8969	.5833E-02
348	2.	40.000	.8934	.3940E-02
346	1.	41.000	.8916	.1981E-02
345	2.	42.000	.8881	.3977E-02
343	2.	43.000	.8845	.3996E-02
341	1.	44.000	.8827	.2015E-02
340	1.	45.000	.8810	.2021E-02
339	1.	46.000	.8792	.2028E-02
338	2.	47.000	.8756	.4071E-02
336	2.	48.000	.8720	.4116E-02
334	1.	49.000	.8702	.2074E-02
333	2.	50.000	.8666	.4163E-02
331	3.	51.000	.8611	.6285E-02
328	1.	53.000	.8593	.2130E-02
327	1.	54.000	.8575	.2139E-02
326	1.	60.000	.8556	.2148E-02
325	1.	62.000	.8538	.2160E-02
324	2.	63.000	.8501	.4332E-02
322	1.	64.000	.8482	.2196E-02
321	2.	65.000	.8445	.4417E-02
319	1.	66.000	.8426	.2236E-02
318	1.	67.000	.8407	.2240E-02
317	3.	68.000	.8351	.6729E-02
314	2.	70.000	.8313	.4538E-02
312	2.	72.000	.8275	.4556E-02
310	1.	73.000	.8256	.2296E-02
309	1.	74.000	.8237	.2305E-02
308	1.	76.000	.8218	.2311E-02

307	2.	85.000	.8180	.4642E-02
305	1.	86.000	.8161	.2331E-02
304	1.	89.000	.8142	.2335E-02
303	1.	90.000	.8123	.2343E-02
302	1.	100.000	.8104	.2349E-02
301	1.	102.000	.8085	.2360E-02
300	1.	105.000	.8066	.2368E-02
299	1.	106.000	.8046	.2374E-02
298	1.	108.000	.8027	.2385E-02
297	1.	114.000	.8008	.2394E-02
296	1.	118.000	.7989	.2397E-02
295	1.	121.000	.7970	.2404E-02
294	3.	122.000	.7912	.7238E-02
291	1.	127.000	.7893	.2443E-02
290	1.	128.000	.7873	.2466E-02
289	2.	136.000	.7835	.4947E-02
287	2.	137.000	.7795	.5014E-02
285	2.	138.000	.7756	.5052E-02
283	1.	139.000	.7736	.2544E-02
282	1.	145.000	.7717	.2554E-02
281	2.	146.000	.7677	.5122E-02
279	1.	147.000	.7657	.2581E-02
277	1.	158.000	.7637	.2605E-02
276	1.	161.000	.7618	.2614E-02
274	1.	171.000	.7597	.2639E-02
273	1.	174.000	.7577	.2650E-02
270	1.	181.000	.7557	.2672E-02
268	1.	189.000	.7537	.2693E-02
267	1.	191.000	.7516	.2701E-02
266	2.	198.000	.7476	.5422E-02
264	1.	202.000	.7455	.2737E-02
263	1.	204.000	.7435	.2748E-02
262	1.	205.000	.7414	.2759E-02
259	1.	221.000	.7394	.2791E-02
258	1.	228.000	.7373	.2799E-02
256	1.	231.000	.7352	.2816E-02
249	1.	253.000	.7331	.2895E-02
246	1.	263.000	.7310	.2924E-02
245	1.	265.000	.7288	.2941E-02
243	1.	275.000	.7267	.2965E-02
242	1.	281.000	.7245	.2974E-02
240	1.	282.000	.7223	.3020E-02
235	1.	293.000	.7201	.3093E-02
226	1.	322.000	.7178	.3212E-02
225	1.	325.000	.7154	.3238E-02
224	1.	327.000	.7131	.3246E-02
223	1.	328.000	.7108	.3255E-02
220	1.	344.000	.7085	.3284E-02
219	1.	347.000	.7061	.3296E-02
217	1.	350.000	.7038	.3323E-02
216	2.	362.000	.6991	.6661E-02
211	1.	373.000	.6967	.3419E-02
209	2.	382.000	.6919	.6892E-02
207	1.	387.000	.6895	.3478E-02
204	1.	402.000	.6871	.3510E-02
203	1.	409.000	.6847	.3530E-02
202	1.	414.000	.6823	.3542E-02
200	1.	416.000	.6798	.3582E-02
199	2.	425.000	.6750	.7200E-02
197	1.	426.000	.6725	.3637E-02

193	1.	431.000	.6700	.3703E-02
191	1.	442.000	.6675	.3764E-02
183	1.	471.000	.6649	.3933E-02
182	1.	473.000	.6623	.3951E-02
177	1.	497.000	.6596	.4065E-02
174	1.	513.000	.6568	.4139E-02
172	1.	537.000	.6541	.4177E-02
170	2.	543.000	.6486	.8458E-02
168	1.	547.000	.6458	.4302E-02
167	1.	551.000	.6430	.4348E-02
159	1.	592.000	.6401	.4538E-02
156	1.	600.000	.6371	.4624E-02
154	1.	615.000	.6342	.4669E-02
153	1.	617.000	.6312	.4692E-02
152	1.	624.000	.6282	.4706E-02
151	1.	628.000	.6253	.4757E-02
149	1.	632.000	.6222	.4820E-02
145	1.	655.000	.6192	.4937E-02
140	1.	695.000	.6160	.5080E-02
135	1.	728.000	.6128	.5227E-02
134	3.	730.000	.6032	.1583E-01
120	1.	826.000	.5996	.5967E-02
119	1.	836.000	.5960	.6030E-02
118	1.	850.000	.5923	.6126E-02
115	1.	897.000	.5886	.6275E-02
112	1.	912.000	.5848	.6462E-02
110	1.	929.000	.5810	.6589E-02
104	1.	986.000	.5770	.6921E-02
100	1.	994.000	.5729	.7116E-02
96	1.	1024.000	.5686	.7494E-02
94	1.	1051.000	.5642	.7772E-02
88	1.	1150.000	.5596	.8138E-02
85	1.	1203.000	.5550	.8360E-02
82	1.	1218.000	.5502	.8619E-02
78	1.	1301.000	.5453	.9017E-02
74	1.	1350.000	.5401	.9423E-02
73	1.	1352.000	.5349	.9685E-02
71	2.	1384.000	.5242	.2017E-01
66	1.	1478.000	.5186	.1076E-01
62	1.	1535.000	.5127	.1136E-01
60	1.	1548.000	.5068	.1169E-01
58	1.	1582.000	.5007	.1196E-01
57	1.	1583.000	.4947	.1218E-01
56	1.	1592.000	.4886	.1236E-01
54	1.	1601.000	.4824	.1276E-01
53	1.	1605.000	.4761	.1313E-01
51	1.	1627.000	.4696	.1367E-01
49	1.	1634.000	.4630	.1411E-01
43	1.	1996.000	.4557	.1594E-01
33	1.	2143.000	.4465	.2033E-01
29	1.	2268.000	.4365	.2260E-01
26	1.	2475.000	.4256	.2528E-01
22	1.	2627.000	.4129	.3002E-01
16	1.	2878.000	.3960	.4157E-01
15	1.	2949.000	.3780	.4645E-01
7	1.	3707.000	.3472	.8410E-01
5	1.	3942.000	.3085	.1166

APPENDIX 21-H

ESTIMATED LIFE TABLE FOR HEART TRANSPLANT RECIPIENTS
TRANSPLANT PERIOD 1968-1973

NUMBER AT RISK	NUMBER FAILING	TIME	EST. SURV PROB	EST. HAZ RATE
409	10.	1.000	.9681	.3236E-01
399	5.	2.000	.9521	.1661E-01
394	2.	3.000	.9458	.6718E-02
392	5.	7.000	.9299	.1689E-01
387	1.	8.000	.9267	.3418E-02
386	3.	9.000	.9172	.1028E-01
383	2.	10.000	.9109	.6907E-02
381	2.	11.000	.9046	.6957E-02
379	1.	12.000	.9015	.3500E-02
378	1.	13.000	.8983	.3512E-02
377	1.	14.000	.8951	.3523E-02
376	2.	15.000	.8888	.7064E-02
374	3.	17.000	.8794	.1070E-01
371	3.	21.000	.8699	.1079E-01
368	2.	22.000	.8636	.7241E-02
366	1.	23.000	.8605	.3657E-02
365	3.	25.000	.8511	.1099E-01
362	1.	26.000	.8479	.3714E-02
361	1.	27.000	.8448	.3731E-02
360	1.	28.000	.8416	.3737E-02
359	3.	29.000	.8322	.1123E-01
356	1.	30.000	.8291	.3783E-02
355	2.	31.000	.8228	.7586E-02
353	2.	36.000	.8165	.7615E-02
351	3.	39.000	.8072	.1148E-01
348	2.	40.000	.8010	.7755E-02
346	1.	41.000	.7979	.3899E-02
345	2.	42.000	.7916	.7827E-02
343	2.	43.000	.7854	.7866E-02
341	1.	44.000	.7823	.3966E-02
340	1.	45.000	.7792	.3978E-02
339	1.	46.000	.7761	.3992E-02
338	2.	47.000	.7699	.8014E-02
336	2.	48.000	.7637	.8101E-02
334	1.	49.000	.7606	.4082E-02
333	2.	50.000	.7544	.8194E-02
331	3.	51.000	.7451	.1237E-01
328	1.	53.000	.7420	.4193E-02
327	1.	54.000	.7389	.4211E-02
326	1.	60.000	.7357	.4228E-02
325	1.	62.000	.7326	.4252E-02
324	2.	63.000	.7264	.8528E-02
322	1.	64.000	.7233	.4322E-02
321	2.	65.000	.7170	.8694E-02
319	1.	66.000	.7138	.4400E-02
318	1.	67.000	.7107	.4408E-02
317	3.	68.000	.7014	.1325E-01
314	2.	70.000	.6951	.8932E-02
312	2.	72.000	.6889	.8967E-02
310	1.	73.000	.6858	.4519E-02
309	1.	74.000	.6827	.4536E-02

308	1.	76.000	.6796	.4548E-02
307	2.	85.000	.6734	.9136E-02
305	1.	86.000	.6703	.4589E-02
304	1.	89.000	.6672	.4596E-02
303	1.	90.000	.6642	.4612E-02
302	1.	100.000	.6611	.4624E-02
301	1.	102.000	.6580	.4646E-02
300	1.	105.000	.6550	.4661E-02
299	1.	106.000	.6519	.4673E-02
298	1.	108.000	.6489	.4695E-02
297	1.	114.000	.6458	.4712E-02
296	1.	118.000	.6428	.4718E-02
295	1.	121.000	.6398	.4733E-02
294	3.	122.000	.6307	.1425E-01
291	1.	127.000	.6277	.4809E-02
290	1.	128.000	.6246	.4854E-02
289	2.	136.000	.6186	.9738E-02
287	2.	137.000	.6125	.9869E-02
285	2.	138.000	.6064	.9943E-02
283	1.	139.000	.6034	.5007E-02
282	1.	145.000	.6004	.5028E-02
281	2.	146.000	.5943	.1008E-01
279	1.	147.000	.5913	.5080E-02
277	1.	158.000	.5883	.5127E-02
276	1.	161.000	.5853	.5145E-02
274	1.	171.000	.5823	.5195E-02
273	1.	174.000	.5792	.5217E-02
270	1.	181.000	.5762	.5259E-02
268	1.	189.000	.5731	.5302E-02
267	1.	191.000	.5701	.5315E-02
266	2.	198.000	.5640	.1067E-01
264	1.	202.000	.5610	.5387E-02
263	1.	204.000	.5580	.5409E-02
262	1.	205.000	.5550	.5431E-02
259	1.	221.000	.5519	.5493E-02
258	1.	228.000	.5489	.5510E-02
256	1.	231.000	.5459	.5543E-02
249	1.	253.000	.5428	.5699E-02
246	1.	263.000	.5396	.5756E-02
245	1.	265.000	.5365	.5790E-02
243	1.	275.000	.5334	.5835E-02
242	1.	281.000	.5303	.5855E-02
240	1.	282.000	.5271	.5944E-02
235	1.	293.000	.5239	.6087E-02
226	1.	322.000	.5206	.6322E-02
225	1.	325.000	.5173	.6374E-02
224	1.	327.000	.5140	.6388E-02
223	1.	328.000	.5107	.6407E-02
220	1.	344.000	.5075	.6465E-02
219	1.	347.000	.5042	.6487E-02
217	1.	350.000	.5009	.6542E-02
216	2.	362.000	.4944	.1311E-01
211	1.	373.000	.4910	.6730E-02
209	2.	382.000	.4844	.1357E-01
207	1.	387.000	.4811	.6845E-02
204	1.	402.000	.4778	.6909E-02
203	1.	409.000	.4745	.6949E-02
202	1.	414.000	.4712	.6971E-02
200	1.	416.000	.4679	.7050E-02
199	2.	425.000	.4613	.1417E-01

197	1.	426.000	.4580	.7159E-02
193	1.	431.000	.4547	.7288E-02
191	1.	442.000	.4513	.7409E-02
183	1.	471.000	.4478	.7742E-02
182	1.	473.000	.4444	.7777E-02
177	1.	497.000	.4408	.8000E-02
174	1.	513.000	.4372	.8147E-02
172	1.	537.000	.4337	.8221E-02
170	2.	543.000	.4265	.1665E-01
168	1.	547.000	.4229	.8469E-02
167	1.	551.000	.4193	.8558E-02
159	1.	592.000	.4156	.8931E-02
156	1.	600.000	.4118	.9102E-02
154	1.	615.000	.4080	.9190E-02
153	1.	617.000	.4043	.9235E-02
152	1.	624.000	.4005	.9262E-02
151	1.	628.000	.3968	.9364E-02
149	1.	632.000	.3931	.9487E-02
145	1.	655.000	.3893	.9718E-02
140	1.	695.000	.3854	.9999E-02
135	1.	728.000	.3814	.1029E-01
134	3.	730.000	.3697	.3117E-01
120	1.	826.000	.3654	.1174E-01
119	1.	836.000	.3611	.1187E-01
118	1.	850.000	.3567	.1206E-01
115	1.	897.000	.3524	.1235E-01
112	1.	912.000	.3479	.1272E-01
110	1.	929.000	.3434	.1297E-01
104	1.	986.000	.3388	.1362E-01
100	1.	994.000	.3341	.1401E-01
96	1.	1024.000	.3292	.1475E-01
94	1.	1051.000	.3242	.1530E-01
88	1.	1150.000	.3190	.1602E-01
85	1.	1203.000	.3138	.1645E-01
82	1.	1218.000	.3085	.1696E-01
78	1.	1301.000	.3031	.1775E-01
74	1.	1350.000	.2975	.1855E-01
73	1.	1352.000	.2919	.1906E-01
71	2.	1384.000	.2805	.3970E-01
66	1.	1478.000	.2746	.2118E-01
62	1.	1535.000	.2685	.2235E-01
60	1.	1548.000	.2624	.2301E-01
58	1.	1582.000	.2563	.2355E-01
57	1.	1583.000	.2502	.2398E-01
56	1.	1592.000	.2442	.2434E-01
54	1.	1601.000	.2381	.2512E-01
53	1.	1605.000	.2320	.2584E-01
51	1.	1627.000	.2259	.2690E-01
49	1.	1634.000	.2197	.2777E-01
43	1.	1996.000	.2129	.3137E-01
33	1.	2143.000	.2045	.4001E-01
29	1.	2268.000	.1956	.4448E-01
26	1.	2475.000	.1861	.4975E-01
22	1.	2627.000	.1754	.5909E-01
16	1.	2878.000	.1615	.8182E-01
15	1.	2949.000	.1473	.9142E-01
7	1.	3707.000	.1247	.1655
5	1.	3942.000	.0988	.2295

APPENDIX 21-I

ESTIMATED LIFE TABLE FOR HEART TRANSPLANT RECIPIENTS
TRANSPLANT PERIOD 1974-1979

NUMBER AT RISK	NUMBER FAILING	TIME	EST. SURV PROB	EST. HAZ RATE
409	10.	1.000	.9781	.2209E-01
399	5.	2.000	.9671	.1134E-01
394	2.	3.000	.9626	.4586E-02
392	5.	7.000	.9516	.1153E-01
387	1.	8.000	.9494	.2334E-02
386	3.	9.000	.9427	.7022E-02
383	2.	10.000	.9383	.4716E-02
381	2.	11.000	.9338	.4750E-02
379	1.	12.000	.9316	.2390E-02
378	1.	13.000	.9294	.2398E-02
377	1.	14.000	.9272	.2405E-02
376	2.	15.000	.9227	.4823E-02
374	3.	17.000	.9160	.7305E-02
371	3.	21.000	.9092	.7368E-02
368	2.	22.000	.9048	.4944E-02
366	1.	23.000	.9025	.2497E-02
365	3.	25.000	.8957	.7505E-02
362	1.	26.000	.8935	.2536E-02
361	1.	27.000	.8912	.2547E-02
360	1.	28.000	.8889	.2552E-02
359	3.	29.000	.8821	.7668E-02
356	1.	30.000	.8799	.2583E-02
355	2.	31.000	.8753	.5179E-02
353	2.	36.000	.8708	.5199E-02
351	3.	39.000	.8640	.7839E-02
348	2.	40.000	.8594	.5295E-02
346	1.	41.000	.8571	.2662E-02
345	2.	42.000	.8526	.5344E-02
343	2.	43.000	.8480	.5370E-02
341	1.	44.000	.8457	.2708E-02
340	1.	45.000	.8434	.2716E-02
339	1.	46.000	.8411	.2726E-02
338	2.	47.000	.8365	.5471E-02
336	2.	48.000	.8319	.5531E-02
334	1.	49.000	.8296	.2787E-02
333	2.	50.000	.8249	.5595E-02
331	3.	51.000	.8180	.8447E-02
328	1.	53.000	.8157	.2863E-02
327	1.	54.000	.8133	.2875E-02
326	1.	60.000	.8110	.2887E-02
325	1.	62.000	.8086	.2903E-02
324	2.	63.000	.8039	.5822E-02
322	1.	64.000	.8016	.2951E-02
321	2.	65.000	.7968	.5936E-02
319	1.	66.000	.7944	.3004E-02
318	1.	67.000	.7920	.3010E-02
317	3.	68.000	.7849	.9043E-02
314	2.	70.000	.7801	.6098E-02
312	2.	72.000	.7754	.6122E-02
310	1.	73.000	.7730	.3086E-02
309	1.	74.000	.7706	.3097E-02

308	1.	76.000	.7682	.3105E-02
307	2.	85.000	.7634	.6238E-02
305	1.	86.000	.7610	.3133E-02
304	1.	89.000	.7586	.3138E-02
303	1.	90.000	.7563	.3149E-02
302	1.	100.000	.7539	.3157E-02
301	1.	102.000	.7515	.3172E-02
300	1.	105.000	.7491	.3182E-02
299	1.	106.000	.7467	.3190E-02
298	1.	108.000	.7443	.3206E-02
297	1.	114.000	.7419	.3217E-02
296	1.	118.000	.7395	.3222E-02
295	1.	121.000	.7371	.3231E-02
294	3.	122.000	.7300	.9726E-02
291	1.	127.000	.7276	.3283E-02
290	1.	128.000	.7252	.3314E-02
289	2.	136.000	.7204	.6648E-02
287	2.	137.000	.7156	.6738E-02
285	2.	138.000	.7107	.6788E-02
283	1.	139.000	.7083	.3419E-02
282	1.	145.000	.7059	.3433E-02
281	2.	146.000	.7010	.6883E-02
279	1.	147.000	.6986	.3468E-02
277	1.	158.000	.6961	.3501E-02
276	1.	161.000	.6937	.3513E-02
274	1.	171.000	.6912	.3547E-02
273	1.	174.000	.6888	.3562E-02
270	1.	181.000	.6863	.3591E-02
268	1.	189.000	.6838	.3620E-02
267	1.	191.000	.6814	.3629E-02
266	2.	198.000	.6764	.7286E-02
264	1.	202.000	.6739	.3678E-02
263	1.	204.000	.6714	.3693E-02
262	1.	205.000	.6690	.3708E-02
259	1.	221.000	.6665	.3750E-02
258	1.	228.000	.6640	.3762E-02
256	1.	231.000	.6614	.3785E-02
249	1.	253.000	.6589	.3891E-02
246	1.	263.000	.6563	.3930E-02
245	1.	265.000	.6537	.3953E-02
243	1.	275.000	.6511	.3984E-02
242	1.	281.000	.6485	.3997E-02
240	1.	282.000	.6459	.4058E-02
235	1.	293.000	.6432	.4156E-02
226	1.	322.000	.6404	.4317E-02
225	1.	325.000	.6376	.4352E-02
224	1.	327.000	.6349	.4361E-02
223	1.	328.000	.6321	.4375E-02
220	1.	344.000	.6293	.4414E-02
219	1.	347.000	.6265	.4429E-02
217	1.	350.000	.6237	.4466E-02
216	2.	362.000	.6182	.8952E-02
211	1.	373.000	.6153	.4595E-02
209	2.	382.000	.6097	.9262E-02
207	1.	387.000	.6068	.4673E-02
204	1.	402.000	.6040	.4717E-02
203	1.	409.000	.6011	.4744E-02
202	1.	414.000	.5982	.4759E-02
200	1.	416.000	.5954	.4813E-02
199	2.	425.000	.5896	.9676E-02

197	1.	426.000	.5868	.4887E-02
193	1.	431.000	.5838	.4976E-02
191	1.	442.000	.5809	.5058E-02
183	1.	471.000	.5778	.5286E-02
182	1.	473.000	.5748	.5310E-02
177	1.	497.000	.5716	.5462E-02
174	1.	513.000	.5685	.5563E-02
172	1.	537.000	.5653	.5613E-02
170	2.	543.000	.5589	.1137E-01
168	1.	547.000	.5557	.5782E-02
167	1.	551.000	.5524	.5843E-02
159	1.	592.000	.5491	.6098E-02
156	1.	600.000	.5457	.6214E-02
154	1.	615.000	.5422	.6275E-02
153	1.	617.000	.5388	.6305E-02
152	1.	624.000	.5354	.6324E-02
151	1.	628.000	.5320	.6393E-02
149	1.	632.000	.5286	.6477E-02
145	1.	655.000	.5251	.6635E-02
140	1.	695.000	.5215	.6827E-02
135	1.	728.000	.5179	.7025E-02
134	3.	730.000	.5069	.2128E-01
120	1.	826.000	.5029	.8019E-02
119	1.	836.000	.4988	.8104E-02
118	1.	850.000	.4947	.8233E-02
115	1.	897.000	.4906	.8433E-02
112	1.	912.000	.4863	.8684E-02
110	1.	929.000	.4820	.8855E-02
104	1.	986.000	.4776	.9300E-02
100	1.	994.000	.4730	.9563E-02
96	1.	1024.000	.4683	.1007E-01
94	1.	1051.000	.4634	.1045E-01
88	1.	1150.000	.4584	.1094E-01
85	1.	1203.000	.4532	.1123E-01
82	1.	1218.000	.4480	.1158E-01
78	1.	1301.000	.4426	.1212E-01
74	1.	1350.000	.4370	.1266E-01
73	1.	1352.000	.4314	.1302E-01
71	2.	1384.000	.4198	.2711E-01
66	1.	1478.000	.4138	.1446E-01
62	1.	1535.000	.4075	.1526E-01
60	1.	1548.000	.4012	.1571E-01
58	1.	1582.000	.3947	.1608E-01
57	1.	1583.000	.3883	.1637E-01
56	1.	1592.000	.3819	.1662E-01
54	1.	1601.000	.3754	.1715E-01
53	1.	1605.000	.3688	.1764E-01
51	1.	1627.000	.3621	.1837E-01
49	1.	1634.000	.3553	.1896E-01
43	1.	1996.000	.3478	.2142E-01
33	1.	2143.000	.3384	.2731E-01
29	1.	2268.000	.3282	.3037E-01
26	1.	2475.000	.3172	.3397E-01
22	1.	2627.000	.3047	.4034E-01
16	1.	2878.000	.2880	.5586E-01
15	1.	2949.000	.2705	.6242E-01
7	1.	3707.000	.2413	.1130
5	1.	3942.000	.2059	.1567

APPENDIX 21-J

ESTIMATED LIFE TABLE FOR MALE HEART TRANSPLANT RECIPIENTS

NUMBER AT RISK	NUMBER FAILING	TIME	EST. SURV PROB	EST. HAZ RATE
350	8.	1.000	.9813	.1881E-01
342	4.	2.000	.9719	.9641E-02
338	2.	3.000	.9672	.4870E-02
336	4.	7.000	.9577	.9807E-02
332	1.	8.000	.9554	.2478E-02
331	2.	9.000	.9506	.4975E-02
329	2.	10.000	.9459	.4995E-02
327	1.	11.000	.9435	.2520E-02
326	1.	12.000	.9411	.2527E-02
325	1.	13.000	.9387	.2537E-02
324	1.	14.000	.9364	.2546E-02
323	1.	15.000	.9340	.2554E-02
322	2.	17.000	.9292	.5149E-02
320	3.	21.000	.9220	.7750E-02
317	2.	22.000	.9172	.5206E-02
315	1.	23.000	.9148	.2634E-02
314	3.	25.000	.9076	.7919E-02
311	1.	26.000	.9051	.2682E-02
310	1.	27.000	.9027	.2696E-02
309	1.	28.000	.9003	.2702E-02
308	3.	29.000	.8930	.8122E-02
305	1.	31.000	.8905	.2741E-02
304	2.	36.000	.8856	.5494E-02
302	2.	39.000	.8808	.5528E-02
300	1.	40.000	.8783	.2795E-02
299	1.	41.000	.8758	.2803E-02
298	1.	42.000	.8734	.2816E-02
297	2.	43.000	.8685	.5645E-02
295	1.	44.000	.8660	.2850E-02
294	1.	45.000	.8635	.2860E-02
293	1.	46.000	.8610	.2872E-02
292	2.	47.000	.8561	.5769E-02
290	2.	48.000	.8511	.5843E-02
288	1.	49.000	.8486	.2949E-02
287	2.	50.000	.8436	.5922E-02
285	3.	51.000	.8360	.8951E-02
282	1.	53.000	.8335	.3043E-02
281	1.	54.000	.8310	.3058E-02
280	1.	60.000	.8284	.3073E-02
279	1.	62.000	.8258	.3094E-02
278	2.	63.000	.8207	.6208E-02
276	2.	65.000	.8156	.6306E-02
274	1.	66.000	.8130	.3199E-02
273	1.	67.000	.8104	.3206E-02
272	3.	68.000	.8026	.9635E-02
269	2.	70.000	.7974	.6512E-02
267	2.	72.000	.7922	.6542E-02
265	1.	74.000	.7896	.3302E-02
264	2.	85.000	.7843	.6621E-02
262	1.	86.000	.7817	.3328E-02
261	1.	89.000	.7791	.3335E-02

260	1.	90.000	.7765	.3348E-02
259	1.	100.000	.7739	.3359E-02
258	1.	102.000	.7713	.3377E-02
257	1.	105.000	.7687	.3390E-02
256	1.	106.000	.7661	.3400E-02
255	1.	108.000	.7635	.3420E-02
254	1.	118.000	.7609	.3434E-02
253	1.	121.000	.7582	.3446E-02
252	3.	122.000	.7504	.1038E-01
249	1.	136.000	.7478	.3512E-02
248	2.	137.000	.7425	.7087E-02
246	1.	138.000	.7398	.3576E-02
245	1.	139.000	.7372	.3594E-02
244	1.	145.000	.7345	.3611E-02
243	2.	146.000	.7292	.7244E-02
241	1.	147.000	.7266	.3655E-02
239	1.	158.000	.7239	.3695E-02
238	1.	161.000	.7212	.3709E-02
236	1.	171.000	.7185	.3752E-02
235	1.	174.000	.7158	.3770E-02
232	1.	181.000	.7131	.3806E-02
230	1.	189.000	.7103	.3843E-02
229	1.	191.000	.7076	.3855E-02
228	1.	198.000	.7049	.3873E-02
227	1.	202.000	.7021	.3891E-02
226	1.	204.000	.6994	.3910E-02
225	1.	205.000	.6966	.3928E-02
222	1.	228.000	.6939	.3981E-02
216	1.	253.000	.6910	.4077E-02
213	1.	265.000	.6882	.4125E-02
211	1.	275.000	.6853	.4163E-02
210	1.	281.000	.6825	.4179E-02
209	1.	282.000	.6796	.4222E-02
204	1.	293.000	.6767	.4340E-02
195	1.	322.000	.6736	.4536E-02
194	1.	325.000	.6705	.4579E-02
193	1.	328.000	.6674	.4591E-02
190	1.	344.000	.6644	.4639E-02
189	1.	347.000	.6613	.4657E-02
187	1.	350.000	.6582	.4703E-02
186	2.	362.000	.6520	.9430E-02
181	1.	373.000	.6488	.4862E-02
179	2.	382.000	.6425	.9814E-02
177	1.	387.000	.6393	.4960E-02
174	1.	402.000	.6361	.5015E-02
173	1.	409.000	.6329	.5048E-02
172	1.	414.000	.6297	.5068E-02
170	1.	416.000	.6265	.5136E-02
169	2.	425.000	.6200	.1033E-01
167	1.	426.000	.6168	.5230E-02
164	1.	431.000	.6135	.5318E-02
162	1.	442.000	.6102	.5423E-02
156	1.	471.000	.6068	.5640E-02
152	1.	497.000	.6033	.5756E-02
149	1.	513.000	.5997	.5880E-02
147	1.	537.000	.5962	.5943E-02
145	2.	543.000	.5890	.1206E-01
143	1.	551.000	.5854	.6154E-02
136	1.	592.000	.5817	.6429E-02
133	1.	600.000	.5778	.6573E-02

131	1.	615.000	.5740	.6648E-02
130	1.	617.000	.5702	.6686E-02
129	1.	624.000	.5664	.6709E-02
128	1.	628.000	.5625	.6797E-02
126	1.	632.000	.5587	.6903E-02
123	1.	655.000	.5547	.7039E-02
120	1.	695.000	.5508	.7171E-02
115	1.	728.000	.5467	.7415E-02
114	3.	730.000	.5345	.2250E-01
103	1.	826.000	.5300	.8432E-02
102	1.	850.000	.5255	.8536E-02
99	1.	897.000	.5209	.8775E-02
96	1.	912.000	.5162	.9079E-02
95	1.	929.000	.5115	.9179E-02
92	1.	986.000	.5067	.9462E-02
86	1.	1024.000	.5016	.9960E-02
84	1.	1051.000	.4965	.1037E-01
78	1.	1150.000	.4911	.1091E-01
75	1.	1203.000	.4856	.1124E-01
72	1.	1218.000	.4800	.1163E-01
68	1.	1301.000	.4741	.1223E-01
64	1.	1350.000	.4681	.1285E-01
63	1.	1352.000	.4619	.1325E-01
61	2.	1384.000	.4492	.2775E-01
57	1.	1478.000	.4426	.1475E-01
55	1.	1535.000	.4359	.1527E-01
53	1.	1548.000	.4291	.1577E-01
51	1.	1582.000	.4222	.1618E-01
49	1.	1601.000	.4152	.1669E-01
47	1.	1627.000	.4079	.1769E-01
45	1.	1634.000	.4005	.1830E-01
39	1.	1996.000	.3922	.2086E-01
30	1.	2143.000	.3820	.2636E-01
27	1.	2268.000	.3711	.2868E-01
24	1.	2475.000	.3593	.3225E-01
20	1.	2627.000	.3456	.3870E-01
14	1.	2878.000	.3271	.5488E-01
13	1.	2949.000	.3073	.6200E-01
7	1.	3707.000	.2775	.1012
5	1.	3942.000	.2407	.1402

APPENDIX 21-K

ESTIMATES LIFE TABLE FOR FEMALE HEART TRANSPLANT RECIPIENTS

NUMBER AT RISK	NUMBER FAILING	TIME	EST. SURV PROB	EST. HAZ RATE
59	2.	1.000	.9667	.3379E-01
57	1.	2.000	.9499	.1747E-01
56	1.	7.000	.9332	.1773E-01
55	1.	9.000	.9165	.1803E-01
54	1.	11.000	.8997	.1847E-01
53	1.	15.000	.8828	.1893E-01
52	1.	17.000	.8659	.1931E-01
51	1.	30.000	.8487	.2004E-01
50	1.	31.000	.8315	.2041E-01
49	1.	39.000	.8144	.2066E-01
48	1.	40.000	.7973	.2118E-01
47	1.	42.000	.7803	.2157E-01
46	1.	64.000	.7633	.2200E-01
45	1.	73.000	.7460	.2289E-01
44	1.	76.000	.7287	.2344E-01
43	1.	114.000	.7112	.2417E-01
42	1.	127.000	.6940	.2439E-01
41	1.	128.000	.6762	.2592E-01
40	1.	136.000	.6585	.2651E-01
39	1.	138.000	.6406	.2751E-01
38	1.	198.000	.6229	.2800E-01
37	1.	221.000	.6050	.2902E-01
36	1.	231.000	.5873	.2961E-01
33	1.	263.000	.5685	.3251E-01
31	1.	327.000	.5486	.3545E-01
27	1.	473.000	.5272	.3972E-01
25	1.	547.000	.5044	.4400E-01
17	1.	836.000	.4722	.6545E-01
12	1.	994.000	.4292	.9473E-01
7	1.	1583.000	.3579	.1786
6	1.	1592.000	.2900	.2064
5	1.	1605.000	.2206	.2667

CHAPTER 22

A COMPARISON OF THE SURVIVAL OF RECIPIENTS AND NONRECIPIENTS OF HEART TRANSPLANTS: A CONCEPTUAL REVIEW AND PRELIMINARY ANALYSIS

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A. INTRODUCTION

As demonstrated in the preceding chapter, most patients undergoing heart transplantation have their lives extended. It is clearly difficult to argue that people do not benefit from a heart transplant. Cardiac transplant surgeons are convinced that the procedure saves the lives of people who would have otherwise died. For example, our analysis of the survival of all male patients from the six heart transplant centers participating in the National Heart Transplantation Study shows that 65 percent of them will survive one year, 54 percent, two years, 50 percent three years, 45 percent four years, and 39 percent five years.

Survival rates for various time periods, as reported by the Stanford group, are summarized in Table 22-1. As shown, patient survival has continued to improve over the years. It is believed that the improvement in patient survival can be attributed to many factors including: (1) refinement of patient selection criteria, (2) the introduction and use of rabbit antihuman thymocyte globulin for immune suppression, (3) T-lymphocyte monitoring for the early diagnosis of rejection, (4) use of transvenous right ventricular endomyocardial biopsy to diagnose and confirm the severity of graft rejection, (5) use of retransplantation, and (6) the use of cyclosporine for immunosuppression.

Despite the apparent gains in patient survival, statisticians continue to debate the alleged lifesaving benefits of heart transplantation (Gail, 1972; Mantel and Byar, 1974; Turnbull et al., 1974; Brown et al., 1974; Crowley and Hu, 1977; Kalbfleisch and

Table 22-1
Heart Transplant Survival Rates Associated
With Different Time Periods

	SURVIVAL YEAR					
PERIOD	1	2	3	4	5	NUMBER OF PATIENTS
1968-1981	57	48	42	35	30	(206)
1968-1974	44	35	27	21	18	(66)
1974-1982	63	55	51	44	39	(140)

SOURCE: Pennock et al., 1982

Prentice, 1980; Aitkin et al., 1983a; 1983b; Gail, 1983; Crowley and Storer, 1983; Boardman, 1983; Tanner and Wong, 1983; Oakes, 1983; Gaynor, 1983; Beck, 1983). In particular, there appear to be differences in opinion as to what constitutes an adequate control group for assessing the life-prolonging ability of heart transplantation. Previous analyses by cardiac transplant teams have, for example, used as a control group those patients selected for heart transplantation but who fail to receive a new heart. Gail (1972), however, was the first to argue that this was not a proper control group since the "...principal reason a transplant candidate does not receive a heart is that he dies before a donor can be found" (Turnbull et al., 1974:74). It is felt that this introduces an unreasonable bias since the survival of treated patients is compared with that of untreated controls. This approach is problematic because it fails to "...make allowance for the fact that the treated patient must have at least survived from time of diagnosis to time of treatment while no similar requirement" is made of the untreated controls (Mantel and Byar, 1974:81). Gail's (1972) argument has been further characterized by Aitkin et al. (1983a:264) as follows:

> Gail notes a problem with selection bias: the nontransplant patients are those who die while waiting for a heart, while transplant patients are those who survive until a suitable heart is found. Very high risk patients generally do not survive the waiting period; thus survival appears better in the transplant group because an undue proportion of "high risk" patients is assigned to the nontransplant group by virtue of their failure to survive the waiting period. Gail concludes that the advantage attributed to transplant is almost certainly due entirely to selection bias.

The paper by Gail (1972) has clearly spurred much interst in alternative approaches to the analysis of survival data. The fact that Crowley and Hu (1977) published a collection of data on both recipients and nonrecipients of heart transplants has made these the data of choice for increasingly sophisticated analyses. Unfortunately, there are several deficiencies in the manner in which these data have been used, not to mention the fact that they are terribly outdated for purposes of establishing the survival or the level of benefit, or lack thereof, associated with heart transplantation. This chapter will attempt to correct some of these deficiencies in the conceptualization of the patient selection process. In addition, the relevance of histocompatibility findings to the recipient selection process will be discussed. Next, we underscore the serious problems associated with the use of outdated data to determine the beneficial effect of heart transplantation. Finally, data from the Stanford group as well as the National Heart Transplantation Study are used to demonstrate the fact that cardiac transplantation does prolong life.

B. THE PATIENT SELECTION PROCESS

All established heart transplant programs follow a similar process in the selection of both candidates for, and recipients of heart transplantation. In addition, as described in Chapters 8 and 10 of this report, a fairly uniform set of patient selection criteria are followed at all programs, although there is some variation in the upper age limit of candidates. Some programs use age 50 as the

preferred cutoff, while others are willing to accept patients up to 55 years of age. Generally, the primary consideration is physiological rather than chronological age, however. It is felt that older patients are likely to have comorbid conditions that preclude transplantation and that people who are older have a more difficult time tolerating immunosuppression.

The selection of candidates for heart transplantation is by no means a simple and straightforward process. Many more patients are referred for cardiac transplantation than can be accommodated (Baumgartner et al., 1979). Not all patients, however, meet the prevailing patient selection criteria (see Table 22-2). Copeland and Stinson (1979:8) comment on the patient selection process as follows:

> The selection process of potential recipients may be one of the most difficult in the field of cardiac transplantatiaon. If the paitent is too sick, he may die during or shortly after transplantation, thus deriving no benefit from a costly and time-consuming effort. If, on the other hand, he is not "sick enough," he may die prematurely, the victim of a "successful" heart transplant.

As alluded to above, and shown in Table 22-2, a rather uniform set of patient selection criteria are followed. These criteria have evolved over time and patient survival is clearly associated with the criteria being followed at any point in time. Copeland and Stinson (1979:8) have commented on this as follows:

> The selection criteria have changed as therapy and survival have become clarified. For example, it was stated in 1972 that a recipient might be accepted "only if it is agreed that he faces death in a matter of weeks," whereas the most recent summary from Stanford states that "they (recipients) should have a poor

Table 22-2
Contraindications To Heart Transplantation As Specified By the National Heart, Lung, and Blood Institute's Special Advisory Group

(1) Advancing age--e.g., beyond the age (normally about 50) at which the individual begins to have diminished capacity to withstand postoperative complications;

(2) Severe pulmonary hypertension as reflected, for example, by a pulmonary artery systolic pressure over 65-70mm Hg and exceeding pulmonary artery wedge pressure by about 40 or more mm Hg, or a calculated pulmonary vascular resistance above approximately 6 Wood units (applicable to orthotopic cardiac transplantation because of the limited work capacity of a normal donor right ventricle);

(3) Irreversible and severe hepatic or renal dysfunction (because of the likelihood of exacerbation early postoperatively and because of interference with immunosuppressive regimens);

(4) Active systemic infection (because of the likelihood of exacerbation with initiation of immunosuppression);

(5) Any other systemic disease considered likely to limit or preclude survival and rehabilitation after transplantation;

(6) A history of behavior pattern or psychiatric illness likely to interfere significantly with compliance with a disciplined medical regimen (because a lifelong medical regimen is necessary, requiring multiple drugs several times a day with serious consequences in the event of their interruption or excessive consumption);

(7) Recent and unresolved pulmonary infarction or pulmonary roentgenographic evidence of abnormalities of unclear etiology (because of the likelihood of pulmonary infection or its exacerbation with initiation of immunosuppression under such circumstances);

(8) Insulin-requiring diabetes mellitus (because of exacerbation by chronic corticosteroid therapy);

(9) Symptomatic or documented severe asymptomatic peripheral or cerebrovascular disease (because of observed accelerated progression in some patients after cardiac transplantation and on chronic corticosteroid treatment);

Table 22-2 (Continued)
Contraindications To Heart Transplantation As Specified By
the National Heart, Lung, and Blood Institute's
Special Advisory Group

(10) Acute peptic ulcer disease (because of the likelihood of early postoperative exacerbation);

(11) The absence of adequate external psychosocial supports for either short or long-term bases (because such support is generally necessary during the inevitable waxing and waning of the clinical status of the patient and for adherence to the lifelong medical regimen).

SOURCE: Federal Register Vol. 46, No. 14, Pgs. 7072-7074, Thursday, January 22, 1981.

> prognosis for surviving the next 6-12 months and generally are limited to functional Class IV congestive heart failure." The selection criteria are of critical importance because they exert a crucial influence on survival statistics obtained.

Thus, the criteria used to select patients as well as the patient selection process itself are critical determinants of patient survival.

Patients are often referred to heart transplant programs after an evaluation by a local physician reveals that they have a heart condition that will not respond to conventional medical and surgical management. After the patient has reported to a heart transplant center, additional tests of cardiac and other organ function may be required. In addition, some tests that have been performed previously may be repeated. Oyer and colleagues (1981:199) describe this process at Stanford as follows:

> Evaluation of potential receipients consists principally of a standard history and physical examination, cardiac catheterization, left ventriculography, and coronary angiography. In addition, careful psychosocial assessment is considered important inasmuch as preexistent psychologic abnormalities may be exacerbated after transplantation and interfere importantly with adherence to strict long-term medical regimen. Acceptance as an active transplant candidate is predicated on failure of all other medical or surgical treatment alternatives to provide an outlook for survival of more than a few months.

If the patient is accepted as a candidate, he or she, depending upon their health status, may return home to await the availability of a donor heart, remain at the hospital for medical treatment until a heart becomes available, or, in the extremely rare case, be transplanted immediately if a heart becomes available and no other

candidate is awaiting transplant. Most frequently, the patient enters a pool of eligible candidates, all of whom are in need of cardiac transplantation. The patients, however, may differ with respect to health status--some patients are much sicker than others. The number of persons awaiting heart transplantation at any one transplant program is generally very small--fewer than five.

When a donor heart becomes available, the general idea is that it will go to the sickest person who is in the candidate pool. If a patient becomes too sick to undergo the procedure, they are routinely taken off the transplant list. A few patients given candidacy status will occasionally regain sufficient cardiac function to warrant removal from the candidate pool. Such patients are considered to be deselected. Thus, the candidate pool is in a state of flux with patients entering and departing the pool for a variety of reasons. It is also the case, however, that the overall health status of patients in the candidate pool can vary considerably. At one point in time, for example, all patients in the candidate pool may be desperately ill, while at other times, all candidates may be in better health and can afford a longer waiting time for a donor heart. In short, all patients are expected to live for less than six months when admitted to the candidate pool, but some patients are sicker than others. Few attempts have been made to establish the precise health status of patients awaiting cardiac transplantation and this, of course, undermines the validity of many statistical studies.

As noted, more patients are referred for cardiac transplantation than are accepted as heart transplant candidates and eventually become

heart transplant recipients. It is noteworthy that the outcomes of referred patients are many. For example, Table 22-3, summarizes the Stanford experience with heart transplant referrals for a one-year period. As shown, there are two major outcome categories. The patient may be rejected for a heart transplant or they may be accepted. Patients who are rejected are of little interest since they failed to meet the criteria for the procedure. Of those patients who are accepted, however, they may have one of several outcomes. They may die awaiting a donor, they may be deselected should they regain adequate cardiac function, they may be transplanted, or, at any one point in time they may be a candidate for heart transplantation who is awaiting the availability of a donor organ. Of these patients, those of greatest interest include patients who died awaiting a donor and those that receive a heart transplant. The deselected patients are of little interest because they regained cardiac function and no longer require heart transplantation. The patients who continue to await transplantation are of limited interest since their final outcome--death or transplantation--is unknown nor predictable in advance.

Who makes decisions about recipients? At Stanford, as described by Christopherson (1982:19), the selection group includes "...a cardiologist, clinical social worker, and cardiac surgeon, all of whom have been associated with the transplant group since its beginning and all of whom have direct significant responsibility for direct patient care." Christophersen (1982:20) further notes that:

> Continuity and accountability, inherent in this system, are helpful to patient selection. Continuing care of the recipient provides immediate feedback regarding the wisdom of any given choice, and colleagues have

Table 22-3
Referrals For Cardiac Transplantation During A One-Year Period:
Stanford University Medical Center

EVALUATION STATUS	NUMBER OF PATIENTS
Initial evaluation	234
Rejected	188
Too old	66
Inadequate finances	10
Premature referral	7
Psychosocial problems	24
Other medical contraindications	45
Died while under consideration	32
Referred elsewhere for transplant	4
Further evaluation	46
Rejected	23
Other therapy attempted	14
Died during evaluation	6
Psychosocial problems	2
Other medical contraindications	1
Accepted	23
Died while awaiting donor	3
Deselected	0
Transplanted	14
Waiting transplantation	6

SOURCE: Baumgartner et al., 1979.

> consistently felt free to assess the performance of the selection group. The temptation of accepting more recipients than could be transplanted in a given period of time is countered by the first-hand knowledge that patients will be offered hope--only to die.

As described above, once a patient has been declared a candidate for heart transplantation they enter a pool of candidates and from this pool heart transplant recipients are drawn. There is no evidence that the recipients of heart transplants are less sick than the candidates awaiting transplantation. In fact, it appears that the sicker rather than healthier patients are selected from the pool of candidates when a donor heart becomes available.

Several conclusions can be reached based on the foregoing that cast serious doubt on the validity of many of the previous analyses of the heart transplant data. These conclusions are as follows:

- There is inadequate evidence that a systematic selection bias exists in the selection of heart transplant candidates. Candidates are expected to become increasingly sick as they await the availability of a donor organ. But it is quite possible that on occasion a patient who is less sick than previous candidates may receive a heart transplant. The degree of sickness is not necessarily uniform across all cohorts of candidates. For example, an unusual supply of donor hearts may make it possible to transplant every one in the candidate pool, regardless of how hardy they are.

- The waiting period for a heart transplant is variable, not fixed. Previous analyses of the Stanford data, such as those of Gail, suggest that each patient must await a minimum time period before receiving a transplant. This is simply untrue. The uneven pattern in the availability of donor organs results in waiting periods of variable lengths. Also, shorter waiting periods do not necessarily imply that a patient will live longer. A patient may have a short waiting period if they are referred late in the course of end-stage

cardiac disease. Such a patient could be desperately ill. Also, a donor organ may become available more readily for some patients than for others. Thus, they too have a short waiting period.

- Patient selection criteria may vary from center to center and, thus, patient survival rates may reflect a more conservative approach to heart transplantation at some centers.

- It is improper to include patients who have been "deselected" for heart transplantation in the analysis of nonrecipient survival as was done by Turnbull et al. (1974). Deselected patients are not candidates for a heart transplant--they must be treated in the same manner as patients rejected for heart transplantation.

Clearly, based on the foregoing, there is reason to be suspicious of previous analyses that reportedly show that heart transplantation does not prolong life. A more careful analysis of data that are consistent with the heart transplant candidate and heart transplant recipient selection process is required. The selection of candidates necessarily differs from the selection of recipients. The selection of candidates is not donor-dependent, whereas the selection of recipients depends on donor availability. While the statistical procedures used in the analysis of the survival data are eloquent, the data to which they are applied misrepresent the process by which patients become both candidates for and recipients of heart transplantation.

C. HISTOCOMPATIBILITY FINDINGS AND THE RECIPIENT SELECTION PROCESS

As pointed out by Crowley and Hu (1977), many analyses of the Stanford heart transplant data are unnecessarily simplistic. Many reports consist of little more than simple actuarial analyses.

Clearly, it is of value to take into consideration the simultaneous effect of several covariates and "...to see on what values of these covariates, if any, transplantation is likely to prolong survival." To accomplish this, Crowley and Hu (1977) used the techniques of Cox (1972; Cox and Oakes, 1984) and Breslow (1974). The following variables were included in their analyses: (1) age of acceptance for heart transplantation (2) age at time of transplant, (3) waiting time for transplantation, (4) experience with previous open-heart surgery, (5) histocompatibility findings (e.g., HLA mismatches).

Of these variables, there appears to be considerable confusion surrounding the importance of histocompatibility data and how these are likely to impact upon patient survival as well as the patient selection process. With the exception of the lymphocyte crossmatch test, all remaining histocompatibility tests are performed retrospectively rather than prospectively. Oyer et al. (1981) describe the situation as follows:

> An array of systems for matching cardiac donors to recipients has been investigated during the past decade. for a variety of reasons, however, only three have proved useful and/or practical in the case of cardiac transplantation. These include ABO blood type compatibility, negativity of the lymphocyte crossmatch, and compatibility for the human lymphocyte antigen HLA-A2. The apparent adverse influence of an A2 antigen mismatch on the rate of development of allograft coronary athersclerosis has been substantiated by ongoing data analysis among long-term survivors of cardiac transplantation. Matching for other HLA antigens, including those of the D locus, is not currently practical inasmuch as the recipient pool awaiting operation is small, resulting in a low probability of achievement of a match likely to improve long-term survival. Other matching systems, which require several days to cell culture, have not been useful for the additional reason that cadaver donors cannot be maintained for the requisite time to complete the assay.

With the exception of the test for ABO blood group compatibility, and the lymphocyte crossmatch test, the remaining tests are performed retrospectively after the transplant.

Baumgartner et al. (1979:16-17) have further elaborated upon this as follows:

> Currently, donors and recipients are matched simply on the basis of ABO blood group compatibility and a negative crossmatch between the recipient's serum and the donor's lymphocytes. Ongoing developments in the immunologic characterization of the determinants of immune responsiveness, as well as characterization of the various subpopulations of immunologically competent cells involved in the process of graft rejection, promise to increase the utility of prospective histocompatibility studies in favorably manipulating the outcome of transplantation. In cardiac transplantation, however, such studies remain of limited value, except possibly in the occasional case of retransplantation for intractable acute rejection, the success of which may be inversely correlated with the number of shared HLA antigens between first and second grafts.

Based on the foregoing, it is evident that Mantel and Byar (1974) fail to grasp the process by which histocompatibility is established and they then incorrectly imply that it is likely to affect the patient selection process. They state, for example:

> Seemingly, selection bias should not be important here since all individuals, whether or not eventually receiving transplants, had to meet the same candidacy requirements. But a potential source of selection bias remains--it could be that individuals for whom matching donor hearts were more readily available might differ from those less readily matched.

The truth of the matter is that donor hearts are not tissue typed to recipients in the sophisticated manner envisioned by Mantel and Byar (1974). In kidney transplantation, where considerably more time is

available for histocompatibility testing, many more histocompatibility tests are performed routinely (Wood, 1983).

In short, while tissue matching is considered to have an important effect on patient and graft survival in most organ transplant studies, it is impossible in the case of heart transplantation to assure each patient that they will receive a suitably matched heart. In fact, because of the desperate status of many heart transplant candidates, even a positive lymphocyte crossmatch test is occasionally ignored. This is not the case, however, for renal transplantation where it is felt that a positive crossmatch contributes greatly to hyperacute rejection. This form of rejection is caused by the presence of pre-formed cytotoxic antibodies in the transplant recipient (Wood, 1983:12). Also, it is for this reason that previous blood transfusions are examined as a variable critical to graft and patient survival.

D. CAN OUTDATED DATA BE USED TO ESTABLISH A BENEFICIAL OR NONBENEFICIAL EFFECT OF CARDIAC TRANSPLANTATION?

Unfortunately, there is a tendency among many analysts to become enamored with statistical procedures without carefully considering the data to which they are applied. This, it could now be argued, is the case with the most recent analyses of the Stanford heart transplant data. Statisticians continue to apply new techniques to the analysis of the data initially published by Crowley and Hu (1977). While this may be useful in an examination of the usefulness of new techniques in the analysis of such data, it seems absurd that conclusions such as the following can be reached in a paper published in 1983 that is based on data that are now ten years old:

> With regard to the effect of transplant itself on survival, our results suggest that the immediate short-term effect may be to increase the hazard, especially for older patients who have survived the very hazardous period after acceptance into the program. Ultimately, however, the estimated long-term hazard appears much lower for all patients posttransplant. Despite this contradiction of a proportional hazards assumption, the overall conclusion about the apparent effect of transplant drawn from and examination of the estimated model alone is similar to the conclusion from our estimated proportional hazards model: younger transplanted patients survive longer, especially those entering early in the program. Age is important because it affects posttransplant but not pretransplant survival whereas calendar time is important because the pretransplant survival improved markedly during the first six years of the program. Waiting time is also important, not because it affects posttransplant survival, but because a declining hazard pretransplant means a better prognosis for patients who have survived their waiting period.

At no place in this 1983 article published by Aitkin and coworkers (1983a) is it ever mentioned that these conclusions are based on data that were effectively seven years old at the time they were analyzed. Also, it seems unfortunate that the authors have effectively used waiting time as a proxy measure of health status when better measures of the latter are available. Despite these criticisms, the reanalysis by Aitkin et al (1983a) is useful, but, only to the extent that it is concerned with the application of alternative statistical techniques to the analysis of data that have been analyzed previously in another way.

Over the last decade since the heart transplant data were first published by Crowley and Hu (1977), many advancements have occurred in the field of heart transplantation. The technique of heart transplantation has improved to some extent, patient selection

criteria have evolved further, and new immunosuppressive drugs are available to treat patients. It would be unfortunate, therefore, to conclude that these previous analyses of the data, including that of Aitkin and coworkers (1983a), should be used to establish the level of survival benefit associated with heart transplantation. Clearly, an analysis of more recent data is required to establish survival benefit. Such an analysis is currently being undertaken by Yagi and Crowley (1984), but as of yet the results are unavailable. In lieu of this, data have been obtained from the Stanford group on a large series of patients to demonstrate what clearly appears to be a beneficial effect associated with heart transplantation.

E. DOES CARDIAC TRANSPLANTATION PROLONG LIFE?

As alluded to in the introduction to this chapter, while the statisticians may have some misgivings about the alleged benefits of heart transplantation, there is little doubt about its lifesaving value as far as cardiac transplant surgeons are concerned. The Stanford group, as well as others in the U.S. and abroad, have consistently argued that heart transplantation has saved the lives of many individuals and, in doing so, has also provided a satisfactory quality of life.

The Stanford group continues to report that patients who are selected as candidates for heart transplantation but fail to receive a donor heart die within a year (Copeland and Stinson, 1979). Most of these patients die within two months. Baumgartner et al. (1979:14) have commented on this situation as follows:

> The time interval between acceptance as a candidate and transplantation in our series has averaged 35 days, and has ranged from 0 to 309 days. However, 38 patients died before a suitable donor became available. The average duration of survival in these latter patients averaged 45 days, and ranged from 0 to 340 days.

A 1981 report from the Stanford group by Oyer et al. (1981:203) noted that:

> The genuinely therapeutic nature of the procedure is illustrated by comparison of these data with the observed survival of patients who met all criteria and were therefore accepted as candidates for transplantation, but for whom an appropriate donor organ could not be found. More than 90% died within 3 months after selection, emphasizing the severity of illness in those accepted for transplantation.

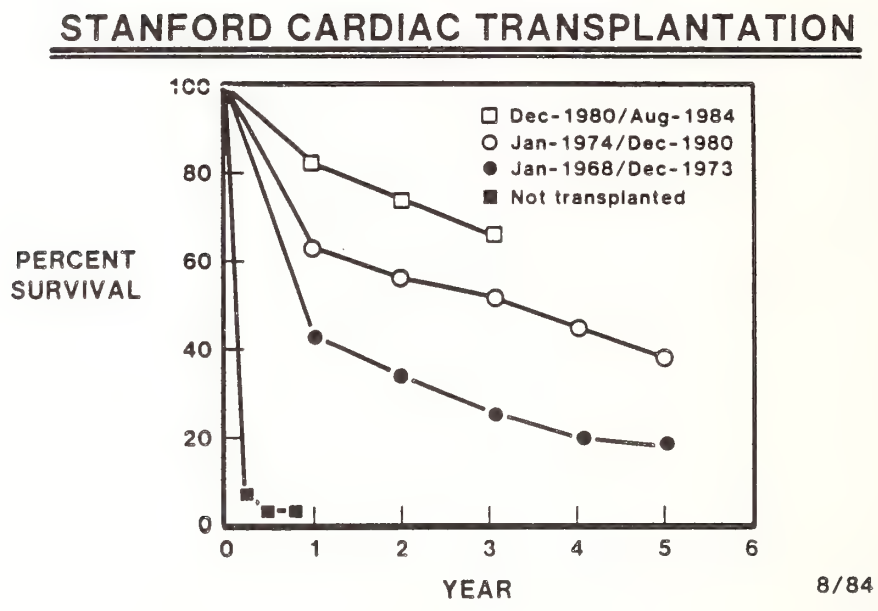
Pennock et al. (1982) reflecting on the Stanford experience states that:

> The survival of an additional 68 patients selected for transplantation during all program years and for whom no donor became available, is less than 5% at six months. Thus, the therapeutic efficacy of cardiac transplantation in terms of patient survival, in our opinion, is not disputable.

Finally, data just obtained from the Stanford group for patients transplanted through July, 1984 are graphically depicted in Figure 22-1. As shown, those patients that were selected as candidates for heart transplantation but were not transplanted all died in less than one year.

Despite the convincing nature of these data, it could still be argued, as did Gail (1972), that the patients who fail to receive a heart transplant are qualitatively different from those that did. In

Figure 22-1
Actuarial Survival Curves of Heart Transplant Recipients
And Those Candidates Who Were Selected For Heart
Transplantation But Who Died Before
A Donor Became Available



other words, as described above, there is some reason to suspect the possiblity of a selection bias. Gail (1972) assumed, based on the very early experiences with heart transplantation, that patients who fail to receive a transplant are at greater risk of death than patients who actually receive one. However, the question left unaddressed by Gail (1972) is whether such a bias, should it exist, be either systematic (constant) or random. For example, if each time a transplant surgeon chooses from the candidate pool a patient that is least sick to receive a heart transplant, this would introduce a systematic bias into the selection process and would clearly jeopardize the validity of the analysis and the conclusions based on that analysis. If, on the other hand, the surgeon selects recipients in a random or near random fashion, the bias is not likely to influence the conclusions that are drawn based on an analysis of survival data. In fact, if surgeons choose the sickest patients from the pool of candidates when a heart becomes available for transplantation, the bias is sytematic but in the direction that is likely to discount the beneficial effect that might be attributed to heart transplantation. As described above in the discussion of the patient selection process, this latter situation would appear to be the case. Sicker, rather than hardier, patients receive heart transplants. Ultimately, the timing of the availability of a donor heart will determine how sick the nonrecipient candidates are when compared with the recipients. In effect, the surgeon's decision to transplant a particular patient is primarily predicated upon the availability of a donor heart and only secondarily on his potentially latent desire to

transplant the hardiest patient in order to bolster survival statistics. There is little evidence to support the claim put forth by Gail (1972) that only healthier patients are transplanted.

F. DISCUSSION AND CONCLUSION

As described here, the statistical literature is at odds with the surgical literature concerning the net survival benefit that can be expected of cardiac transplantation. Statisticians have argued that the advantage attributed to transplantation is almost certainly due entirely to selection bias (Gail, 1972), although two major papers have shown that there is some benefit for younger, healthier transplant recipients (Crowley and Hu, 1977; Aitkin et al., 1983a). While there is some potential for bias when cardiac transplant surgeons select heart transplant recipients (not candidates) it is argued here that this bias may be more random than systematic. If it is, then the selection problem is less significant since random bias introduces fewer problems in the analysis of the data. In fact, it is argued that transplant surgeons may in fact "stack the deck" against themselves since they allegedly choose the sickest rather than hardiest patients to transplant when a donor heart becomes available.

The surgeons have shown rather presuasively that patients who are declared candidates but for whom a donor heart does not become available are unlikely to survive in excess of six months. One report from the Stanford group indicates that 90 percent of these patients are dead within 3 months after selection. The average length of survival for these patients is said to be 45 days. Based on these

findings, proponents of cardiac transplantatiaon have argued that patients yield a net survival benefit.

The fact that the statistical literature presents a rather dim view of heart transplantation can be attributed to many factors. First, the process by which patients are selected for heart transplantation, both candidates and recipients alike, has not always been accurately depicted. Thus, the data upon which at least some of these analyses have been performed are at least modestly deficient. Second, the data are clearly outdated for purposes of establishing the survival benefit, or lack thereof, associated with heart transplantation. For example, the most recent transplant included in the data was performed in 1974. The field of organ transplantation and the immunology associated with it have changed remarkably since 1974. Third, the statisticians seem to fail to recognize the nearly uniform criteria that are used to select cardiac transplant candidates. Recipients are undoubtedly more similar to each other than envisioned by the statisticians. Fourth, recipient selection from the candidate pool is largely a function of health status at the point of decision-making. Unfortunately, the health status of heart transplant candidates is only grossly defined. A proxy measure--waiting time--is used as an indicator of health status. Yet it is clear, however, that waiting time is in part a function of the characteristics of those individuals who constitute the candidate pool. Some candidate pools are made up of healthier patients than other candidate pools. Fifth, there is a tendency among statisticians to include deselected patients in the nonrecipient pool when, in

effect, they should be eliminated from all of the survival analyses. Deselected patients are either temporarily or permanently excluded from consideration for heart transplantation. Sixth, histocompatibility findings are not a critical determinant of which patients are eventually transplanted. All the major HLA findings are ascertained subsequent to transplantation with the exception of the lymphocyte crossmatch. In effect, heart transplant recipients are not tissue-typed in the same manner as kidney transplant recipients.

In conclusion, while not all of the foregoing problems have been rectified in the survival analyses undertaken as part of the National Heart Transplantation Study, some progress has been made. A more sophisticated preliminary analysis of the survival of recipients and nonrecipients of heart transplants is being conducted to determine if there is a net survival benefit associated with cardiac transplantation (Yagi and Crowley, 1984). The Cox proportional hazards model is being used for these analyses, since it permits a proper accounting of all potential sources of bias such as the bias that is introduced if only the healthier heart transplant candidates become the recipients of new hearts (Cox and Oakes, 1984).

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CHAPTER 23

AN OVERVIEW OF QUALITY OF LIFE ASSESSMENT AMONG HEART TRANSPLANT RECIPIENTS

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A. INTRODUCTION

The assessment of quality of life is a complex matter. In fact, it is sometimes argued that it is impossible to meaningfully measure the quality of life of people in the general population, let alone that of people who are chronically or terminally ill. From our point of view this extreme position is to be rejected and, in the future, quality of life assessment amongst people who undergo a variety of therapeutic interventions is likely to become a very important activity. The National Heart Transplantation Study afforded us an opportunity to make such an assessment.

Historically the success of medical interventions has been judged almost solely on the basis of survival. Today, the criteria for judging success often includes some attempt to characterize the degree to which patient outcomes other than survival, such as employment, functional ability, and life satisfaction, are either restored to pretreatment levels or at least are improved to a level that exceeds that at the time treatment was initiated. In short, we have come to expect more of medical treatment than mere survival.

Medical technological advances now permit lives to be sustained that just a few years ago would have been impossible to sustain. In fact, it has become much less clear at precisely what point death occurs (Evans, 1983a; 1983b). As described by Crane (1975), technological changes have affected the very character of illness, permitting the physician to have greater control over the process of dying and the timing of death. She also notes that in less obvious ways, improvements in medical technology have produced increasing

levels of disability in western society (Ford, 1970). Moreover, technology has permitted the survival of more or less severely disabled persons such as diabetics and infants with myelomeningocele who would otherwise have died. While these advances in medicine are clearly dramatic, they thrust into the forefront the issue of quality of life. More frequently than ever before, clinicians and patients are forced to confront what has become known as the quality/quantity of life tradeoff (McNeil et al., 1981; 1982; McNeil and Pauker, 1982). On the one hand, in rendering their judgments, clinicians can decline to offer patients available treatment if the patient is not expected to benefit. On the other hand, patients, upon being offered various therapies, may decline to accept them on the basis of the quality of life they may afford. Thus, the quality/quantity of life tradeoff is one more issue to be considered in the patient/physician encounter.

As alluded to above, a consensus is yet to emerge as to the merit of measuring the quality of life of patients undergoing medical intervention. In the Coronary Artery Surgery Study (CASS), the problems inherent in assessing the quality of life of patients undergoing coronary artery bypass or being medically managed has been characterized by the CASS Principal Investigators and their associates (1983) as follows:

> Quality of life is of substantial importance but it is much more difficult to analyze (than quantity of life) because its descriptors are generally subjective and potentially highly influenced by factors other than the therapeutic intervention. Nevertheless, it is generally accepted that, in the treatment of patients with ischemic

> heart disease, quality of life is improved when there is improved functional status with amelioration of cardiac -related symptoms and a return to gainful employment and recreational activity after intervention. Conversely, quality of life is adversely affected by the need for ancillary supportive treatment such as extensive drug therapy or recurrent hospitalization and by the need for lifestyle modification.

The points being made here are clear. Quality of life has two dimensions--one objective and the other subjective--and quality of life is affected by factors other than medical intervention.

The primary objective of this chapter is to provide an overview of the following three chapters which describe the quality of life of patients who have undergone heart transplantation. Much of the analysis obviously focuses on the results of our survey of living heart transplant recipients. Where appropriate, however, data from deceased heart transplant recipients have also been incorporated into the analyses.

Before providing individual chapter overviews, it is first necessary to develop our conceptual framework for the assessment of quality of life. This framework, previously followed in the National Kidney Dialysis and Kidney Transplantation Study (Evans et al., 1982a; 1982b), is developed in considerable detail below. At the outset of the National Heart Transplantation Study, we made a conscious decision to incorporate the same measures of quality of life that were used in our research on kidney dialysis and kidney transplantation patients. The objective was to yield a data base that would permit comparable analyses of the data.

B. THE BASIS FOR QUALITY OF LIFE ASSESSMENT

1. THE CONCEPTUALIZATION OF QUALITY OF LIFE IN THE NATIONAL KIDNEY DIALYSIS AND KIDNEY TRANSPLANTATION STUDY

In the National Kidney Dialysis and Kidney Transplantation Study we have completed the most exhaustive analysis of the quality of life of kidney dialysis and kidney transplant patients ever undertaken to our knowledge. In that study, we carefully provided operational definitions of quality of life and then measured it for 859 patients from eleven dialysis and transplant centers across the United States. At the outset of the study, our primary goal was to determine which of the available treatment modalities for end-stage renal disease (ESRD) offered patients the highest quality of life at the least cost to the federal government. Over a period of three years, we have completed the quality of life analyses and are now in the process of integrating the appropriate cost analyses.

When we began the National Kidney Dialysis and Kidney Transplantation Study we recognized that numerous studies of the quality of life of ESRD patients showed that quality of life was partially determined by treatment modality. It was often unclear, however, how much of this difference was attributable to the fact that patients on different treatment modalities were qualitatively different (i.e., case-mix differences). In effect, it was felt that some patients did better (or worse) as a function of initial personal and medical characteristics, such as age and education, and health status (e.g., comorbidity) rather than as a result of their treatment modality. Nevertheless, in the absence of evidence to the contrary, clinicians and policymakers were expressing a greater interest in the

identification of those patients who might maximally benefit from the available treatment modalities. Likewise there was a clear interest on behalf of government officials to provide incentives to promote those treatment modalities which enhanced patient outcomes, yet were least costly to the federal government (Evans et al., 1982a; 1982b). Consequently, not only was the cost of treating ESRD a growing concern, but patient quality of life was likely to become a major consideration in deciding the appropriateness of given treatment modalities for particular classes of patients, assuming the existing treatment modalities were complementary, not competitive.

Despite the growing concern over the quality of life of ESRD patients, at the time of our study, the concept remained very nonspecific and, at times, very ellusive. Frequently, published reports used the concepts of disability, rehabilitation, employment status, and health status interchangeably with quality of life. For example, a patient who was working was often characterized as having a higher quality of life than a patient who was not. Similarly, patients who were relatively free of functional impairment were thought to have a higher quality of life than those who were grossly debilitated. Still other studies had incorrectly used patient survival as a suitable indicator of patient quality of life. Such studies assumed that the longer patients survived the better their quality of life. While these objective proxy indicators of life quality were often satisfactory for some purposes, we recognized that they did not exhaust the full-range of conceptual referrants. Instead, we felt quality of life could also be viewed as a patient's

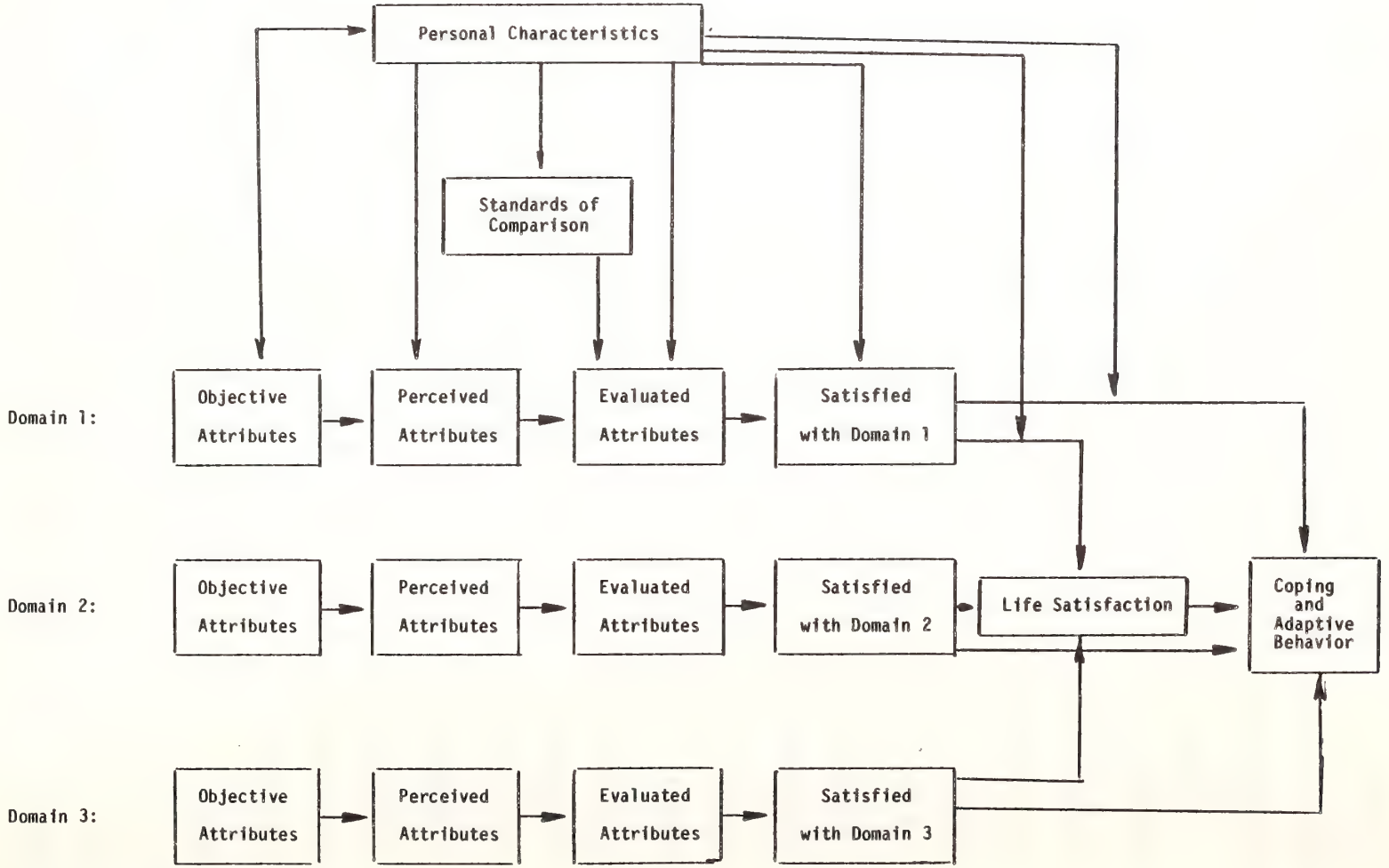
subjective experience with their immediate life circumstances (Andrews and Withey, 1974; 1976; Campbell et al., 1976; Campbell, 1976; Andrews, 1974; Rodgers and Converse, 1975). In this regard it was appropriate to consider the patient's life satisfaction, general well-being, and happiness as indicators of their quality of life.

It was becoming increasingly apparent that many previously used proxy indicators of quality of life, such as employment status, were more correctly envisioned as determinants of patient life satisfaction, well-being, and happiness (Evans et al., 1982a; 1982b). While a patient's quality of life, like that of a person in the general population, was at least partially determined by various sociodemographic factors including age, sex, race, and education (Campbell et al., 1976), numerous other factors were likely to have an influence as well. For example, a patient's satisfaction with their life circumstances including health status, may in part be determined by their level of disability or functional impairment, employment status or work-related disability, and their social environment. Thus, these objective indicators of quality of life were perhaps better envisioned as determinants of the ESRD patient's subjective assessment of their life circumstances. While objective life conditions are informative and important, they may in fact bear little or no relationship to subjective life experiences. Thus, we (Evans et al., 1982b), argued that although it is common to view disability, employment and rehabilitation as an integral part of the patient's quality of life matrix, an assessment of quality of life should include perceptual or subjective indicators as well. One measure of

the success of an approach in treating a condition is the potential the treatment has for restoring an individual to his premorbid functional ability, while compromising as little as possible his subjective quality of life.

Campbell et al. (1976) have argued and persuasively shown that life can be visualized along the lines of various life domain experiences that individuals have. For example, work and family life would be examples of two life domains. In dealing with life experiences, individuals acknowledge that each domain has a set of objective attributes, they perceive these attributes, evaluate their attributes, and ultimately associate some level of satisfaction with each life domain (see Figure 23-1). Taken together, the level of satisfaction the individual experiences across all domains constitutes their overall life satisfaction. It is recognized, however, that an individual's personal characteristics (e.g., age, sex, race, etc.) affect and are affected by the objective attributes of each domain but also these characteristics affect the perceived attributes of each domain, the manner in which the person evaluates these attributes, and their domain-specific satisfaction. Of course, various personal characteristics also influence an individual's expression of overall life satisfaction. It is also apparent that the standards of comparison for evaluating domain-life experiences vary from individual to individual. Thus, in quality of life terms, what one individual is satisfied with, another may not be. It is in precisely this regard that quality of life assessment becomes a complex activity. Campbell

Figure 23-1
A General Quality of Life Model



SOURCE: Campbell et al., 1976.

et al. (1976:15) summarize the problems associated with different standards of comparison as follows:

> While our basic model leaves room for idiosyncrasies of perception and evaluation, it seems likely much variation in viewpoints from individual to individual is in fact patterned along lines by experience, social location, and personality. For example, persons of different ages, races, and income, or urban-rural residence may have characteristically different ways of evaluating the same objective situations, in no small measure because they bring different standards of comparison to bear upon these evaluations. Similarly, people may be characterized by a general optimism or pessimism, and such inclinations to see the best or the worst side of things, along with other attributes of personality, may be expected to influence the way they perceive the world around them. Therefore, in our elaborated model, we would want to recognize that personal characteristics have a significant bearing on every step of our basic model.

Clearly, at this point in development the conceptual model is not flawless, but it does, nonetheless, provide a reasonable basis for quality of life assessment.

2. QUALITY OF LIFE ASSESSMENT IN THE NATIONAL HEART TRANSPLANTATION STUDY

Assessing the quality of life of heart transplant recipients is uniquely different from that of ESRD patients. Most importantly, there are presumably no alternative treatment modalities available to the heart transplant recipient. If there were, they would not be under consideration for a heart transplant since heart transplant candidates, by definition and selection, have a life expectancy of six months or less. Also, all other treatment options must have been exhausted and shown to be futile. In short, without the transplant the patient is expected to die shortly. As a result, it is next to

impossible to evaluate the quality of life of patients who have not undergone heart transplantation but have been successfully managed in another way. It would be possible, however, to evaluate the quality of life of heart transplant recipients prior to their transplant but at this point in their disease trajectory it is perhaps more appropriate to describe their everyday experience as the "quality of death" rather than the quality of life. Most candidates for cardiac transplantation are simply too sick to function.

Elsewhere we have published results which demonstrate that it is reasonable to conceptualize quality of life as having two dimensions: one objective and one subjective (Evans et al., 1984). Excluding patient survival, the objective indicators of quality of life include employment status, ability to work, health status, and functional impairment. The subjective indicators of quality of life, although potentially large in number, include patient well-being, life satisfaction, and psychological affect. In both the National Heart Transplantation Study and the National Kidney Dialysis and Kidney Transplantation Study a large number of quality of life indicators were included in the data collection effort. Results reported here will dwell only on three indicators that were found most useful in the work of Campbell et al. (1976).

Table 23-1 provides a complete listing of all quality of life indicators included in both studies and Appendix 23-A contains the questions that were asked of patients or persons responsible for the care of the patients. As shown here, most of the indicators of

Table 23-1
Quality of Life Indicators Included in the National Kidney Dialysis and Kidney Transplantation Study and the National Heart Transplantation Study

QUALITY OF LIFE INDICATOR	LEVEL OF MEASUREMENT	VALUES	REFERENCE
(A) OBJECTIVE INDICATORS			
Employment Status	Nominal		New
Ability to Work	Interval/Metric	0.0-100.0	Bureau of Census, 1980
Health Status	Interval/Metric	Varies by Scale	Bergner et al., 1981
Functional Impairment	Interval/Metric	1.0-10.0	Karnofsky and Burchenal, 1949
(B) SUBJECTIVE INDICATORS			
General Well-Being Index	Interval/Metric	1.0-6.0	Fazio, 1977
Index of Psychological Affect	Interval/Metric	1.0-7.0	Campbell et al., 1976; 1978
Index of Well-Being	Interval/Metric	2.1-14.7	Campbell et al., 1976; 1978
Overall Life Satisfaction	Interval/Metric	1.7	Campbell et al., 1976; 1978
Positive Affect Scale	Interval/Metric	0-5	Bradburn, 1969
Negative Affect Scale	Interval/Metric	0-5	Bradburn, 1969
Affect Balance Scale	Interval/Metric	1-9	Bradburn, 1969
General Life Satisfaction	Interval/Metric	1.0-2.0	Campbell et al., 1976; 1978
Satisfaction With Marriage	Interval/Metric	1-7	Campbell et al., 1976; 1978
Satisfaction With Sex Life	Interval/Metric	1-7	--
Satisfaction With Family Life	Interval/Metric	1-7	Campbell et al., 1976; 1978
Satisfaction With Savings and Investments	Interval/Metric	1-7	Campbell et al., 1976; 1978
Satisfaction With Standard of Living	Interval/Metric	1-7	Campbell et al., 1976; 1978
Satisfaction With Friendships	Interval/Metric	1-7	Campbell et al., 1976; 1978
Satisfaction With Health	Interval/Metric	1-5	Campbell et al., 1976; 1978
Feeling About Present Life (hard, easy)	Interval/Metric	1-7	Campbell et al., 1976; 1978
Feeling About Present Life (tied down, free)	Interval/Metric	1-7	Campbell et al., 1976; 1978

quality of life were taken from previous studies. The objective indicators were directly incorporated from previous work or adapted for this research. The question on employment status is an exception, however. It was developed specifically for the National Kidney Dialysis and Kidney Transplantation Study and was then incorporated directly into the National Heart Transplantation Study.

The question on ability to work is a standard question used in the annual Health Interview Survey (HIS) conducted by the National Center for Health Statistics (NCHS).

The Sickness Impact Profile (SIP) is a standardized questionnaire that measures sickness-related dysfunction. It is often described as a measure of health status. The SIP consists of 136 questions which are grouped into 12 categories, each describing an area of activity in which dysfunctional behavior may occur (Bergner et al., 1981; 1984; Pollard et al., 1976; Bergner et al., 1976a; 1976b). A score for each of the categories may be calculated, as well as a psychosocial dimension score, a physical dimension score, and an overall SIP score. As the level of dysfunction experienced by the subject rises, so does the SIP score.

Finally, the Karnofsky Index was used to measure the level of physical functioning among patients in the study (Karnofsky and Burchenal, 1949). This scale has been previously used by Gutman et al. (1981) in an earlier study of patients on maintenance dialysis. Scores on this index range from 1 (normal; no complaints; no evidence of disease) to 10 (moribund; fatal process progessing rapidly).

The majority of the subjective indicators of quality of life were taken from the work of Campbell et al. (1976; Campbell and Converse, 1980) at the Institute of Social Research at the University of Michigan. Although the interpretation of most quality of life variables is straightforward, a few comments are in order concerning their construction. Greater detail is provided in Appendix 23-A. As listed in Table 23-1, the first quality of life indicator is the General Well-Being Index which has previously been used in the Health Interview Survey conducted by the National Center for Health Statistics (Fazio, 1977). This index contains ten questions about various aspects of the patient's life. The responses to the questions are summed and then averaged to obtain a mean index score. The Index of Well-Being, a slightly different measure of patient well-being, is obtained by averaging the overall life satisfaction item and the Index of Psychological Affect (see below).

The Index of Psychological Affect is based on eight bipolar items which describe how the patient feels about their present life. Responses to these items are also summed and then averaged to produce a mean score.

The indicator of overall life satisfaction as well as the indicators concerning satisfaction with marriage, sex life, family life, savings and investments, standard of living, and friendships are based on bipolar responses ranging on a scale of one to seven from "very dissatisfied" to "very satisfied." Satisfaction with health is similarly scored on a scale of one to five. Also, the two indicators on feelings concerning patients' present life, "hard versus easy" and

"tied down versus free," are bipolar. For this group of ten indicators, mean or average scores are computed for all patients.

The remaining three scales--the Positive Affect Scale, the Negative Affect Scale, and the Affect Balance Scale--are based on the work of Bradburn and Caplovitz (1965) who conceptualized psychological well-being as having two dimensions, namely positive and negative affect. To measure affect, respondents were asked to respond to a series of questions concerning different pleasurable and unpleasurable experiences they might have had in the past few weeks (e.g., During the past few weeks, did you ever feel very lonely or remote from other people?). Positive affect denotes pleasurable experiences or feelings while negative affect denotes unpleasurable experiences or feelings. Since the two dimensions of affect are independent of one another, knowledge of a person's standing on one dimension does not enable one to predict their position on the other (Bradburn, 1969). Also, since positive and negative affect can be related to other measures of well-being in opposite directions, it is expected that a person high on positive feelings and low on negative feelings would be "very happy," while someone who was low on positive feelilngs and high on negative feelings would be more likely to be "unhappy." Thus, the Affect Balance Scale is thought to be a good indicator of a person's feelings of well-being.

The Positive Affect Scale is constructed by summing patient responses to five questions concerning positive feelings or experiences. The Negative Affect Scale, on the other hand, represents the sum of five questions concerning negative feelings or experiences.

The Affect Balance Scale, with a few standard adjustments, results from transforming the differences in intensity on the Positive Affect Scale and the Negative Affect Scale.

The foregoing summarizes the manner in which quality of life has been assessed in the National Heart Transplantation Study. Multiple measures have been included in the data collection effort given the ellusive nature of the concept being measured. Methodologically, the intent has been to triangulate the evidence to determine if a straightforward concept of quality of life emerges from the data. In this regard, perhaps two of the most significant findings in the National Kidney Dialysis and Kidney Transplantation Study were as follows: (1) it is reasonable to conceptualize quality of life as having both an objective and subjective dimension and (2) when multiple measures of quality of life are considered, a rather clear and consistent picture emerges.

C. AN OVERVIEW OF CHAPTERS 24, 25, AND 26

Chapters 24, 25, and 26 contain detailed analyses of the quality of life of heart transplant recipients. Each chapter focuses on different aspects of quality of life, although Chapter 26 represents an attempt to comparatively assess the quality of life of kidney transplant, kidney dialysis, and heart transplant patients. Below, the intent of each of these chapters is summarized.

1. CHAPTER 24. THE WORK STATUS OF LIVING HEART TRANSPLANT RECIPIENTS

Perhaps the most frequently analyzed patient outcome in studies of therapeutic intervention is work or employment status.

Whether or not a previously working patient has been able to return to work is a primary consideration in the rehabilitation of the patient. In cardiovascular studies, return to work has been a particularly important goal and a frequent indicator of successful intervention (Hammermeister et al., 1979; Rimm et al., 1976; Frick et al., 1979; Barnes et al., 1977; Love, 1980; Rosenfeldt et al., 1983; Jenkins et al., 1983; Stanton et al., 1983), but the results of studies of patients who have undergone bypass surgery have been largely inconsistent. One study has shown, for example, that work status 3 months before surgery or catheterization was the best predictor of continued employment 15 months later (Hammermeister et al., 1979). Other studies have shown that while the great majority of patients are able to resume normal economic and social functioning within six months after bypass surgery, the determinants of return to work are largely present before surgery and that patients, attitudes and expectations play an important role (Jenkins et al., 1983; Stanton et al., 1983). Still other studies have been less optimistic as Love (1980) found that of 34 patients unemployed for 2 months to 24 months before bypass surgery, only 24 percent returned to work following surgery.

Reports on the rehabilitation of heart transplant recipients have been scarce. Published accounts have nonetheless been positive (Christopherson et al., 1976; Christopherson, 1982; Graham et al., 1973; Caves et al., 1973; Barnard, 1975). Christopherson and associates (1976) at Stanford conducted a study of the physical, occupational, and social status of 56 patients who survived six or

more months after cardiac transplantation and found that 91 percent were successfully rehabilitated. Seven percent retained substantial physical disability and two percent experienced psychiatric disability. More recently the Stanford group has reported that of 93 patients who survived for at least 3 months after the operation, 84 (90%) returned to their previous occupations or similar activities (Baumgartner et al., 1979:52).

The experience in England, as reported by English and his associates (1980), has not been nearly as favorable. Of 12 heart transplants performed at Papworth Hospital from January 1979 to July 1980 there were 3 deaths. Of the remaining 9 patients, 6 left the hospital and 3 returned to work. Subsequent reports from English et al. (1983) have been more positive, however.

Based on the available evidence, it appears prudent to analyze the employment status of heart transplant recipients intensively. In Chapter 24, heart transplant recipients are first classified according to the occupations they were engaged in immediately prior to their transplant and, if working, their current occupation. Next, heart transplant recipients are examined according to their pre- and posttransplant employment status. Finally, we examine what employers have done in the past to enable patients to continue to work, despite their heart condition.

2. CHAPTER 25. AN ANALYSIS OF THE OBJECTIVE AND SUBJECTIVE QUALITY OF LIFE OF HEART TRANSPLANT RECIPIENTS

Above we have argued that quality of life has both an objective and subjective dimension. Employment status is an objective quality of life indicator. In Chapter 25, we consider three other objective indicators--ability to work, functional impairment, and

health status. In addition, we examine three indicators of subjective quality of life including life satisfaction, well-being, and psychological affect. There are many other indicators that could have been reported in this Chapter but our attention focuses only on those indicators we consider of primary importance given our past research. Other chapters of this report, particularly Chapter 9, contain descriptive results of the analysis of other subjective indicators.

The results presented in Chapter 25 are particularly important. Heart transplant recipients have never before been the subject of a systematic attempt to assess their subjective quality of life. Previous related attempts to do so have examined the psychosocial adjustment of patients largely from a psychological or psychiatric perspective (Lunde, 1969; Kraft, 1971). While such approaches are useful and provide valuable insights, they do not truly come to grips with how heart transplant recipients view their lives. In this regard it is often assumed that, given their condition, heart transplant recipients necessarily have an inferior subjective quality of life when compared with persons in the general "nonsick" population. Afterall, it is argued, illness clearly diminishes overall quality of life. Our research on kidney dialysis and kidney transplant patients suggests that this is not necessarily the case. In fact, it appears that many chronically ill people are quite capable of adjusting to their life circumstances despite their illness. Consequently, we have found wide divergence in objective and subjective descriptions of quality of life. While on the basis of objective indicators the quality of life of chronically ill patients is notably compromised, an

assessment of subjective quality of life yields an entirely different picture--a picture that confirms the remarkable social and psychological adaptability of human beings.

Ultimately, Chapter 25 provides the basis for the detailed comparative analyses that follow in Chapter 26. In the absence of such comparisons, it is clearly difficult to interpret the results contained in Chapter 25.

3. CHAPTER 26. A COMPARATIVE ANALYSIS OF QUALITY OF LIFE: HEART TRANSPLANTATION, KIDNEY TRANSPLANTATION, AND KIDNEY DIALYSIS

As noted above, at the outset of the National Heart Transplantation Study one of our primary objectives was to collect data that would easily lend themselves to comparative analyses. Over the past three years we have intensively studied the quality of life of both kidney dialysis and kidney transplant patients. The data used in these analyses are now available for comparative analyses. However, even with these data as a basis for reference, our analyses would be inadequate. Any comparisons would only provide insight into how people with a compromised health status view their quality of life. In anticipation of this dilemma, we used measures of quality of life in both the National Heart Transplantation Study and the National Kidney Dialysis and Kidney Transplantation Study which have previously been applied to the general population of the U.S. As a result, it is now possible to make quality of life comparisons of heart transplant recipients with what might be considered a "normal" population. In psychological testing, this is a major goal--the ability to make comparisons with a normal group provides a means by which deviation

can be assessed. In short, we are asking, how does the quality of life of persons with compromised health compare with that of people in the general population? Admittedly, few studies permit such direct comparisons. Although the comparisons presented in Chapter 26 are not flawless, they are substantively important.

It is also noteworthy that the analyses presented in Chapter 26 represent a first step in the cost-effectiveness analysis of heart transplantation. In order to address a variety of issues related to the efficient allocation of resources, various quantitative techniques such as cost-effectiveness and benefit-cost analysis have been developed. These approaches attempt to assign specific numerical values to the benefits of medical interventions of various kinds as well as their costs (Avorn, 1984; Weinstein and Stason, 1977; Warner and Luce, 1982). Once quantified, costs and outcomes are compared to determine which health care intervention represents the most efficient use of available resources. While both cost-benefit and cost-effectiveness analysis measure costs in dollars, cost-effectiveness analysis expresses outcomes in measurable terms (e.g., quality-adjusted life years, number of patients treated), but cost-benefit analysis expresses outcomes in terms of dollars. In this respect, cost-effectiveness analysis has an intuitive appeal over cost-benefit analysis.

Chapter 26 forces us to ask broader questions concerning heart transplantation. Heart transplantation is not the object of abstract assessment in this Chapter. Questions are inevitably raised about accepted standards of therapy. The analyses undertaken here

attempt to resolve the experiment-therapy dilemma. If kidney transplantation and kidney dialysis are considered accepted therapy, then the results presented in Chapter 26 go a considerable distance towards providing an answer to the question of whether heart transplantation is an experimental or therapeutic procedure. If the outcomes of heart transplantation measure up to those of renal transplantation and renal dialysis, then it seems heart transplantation must be granted therapeutic status or the status of renal transplantation and renal dialysis will have to be down graded.

D. CONCLUSION

The assessment of the quality of life of patients undergoing medical treatment is becoming an increasingly important activity. In the National Heart Transplantation Study a concerted attempt has been made to conduct a reasonable quality of life assessment. Quality of life is considered to have both an objective and subjective dimension. In Chapters 24, 25, and 26 various indicators of quality of life are analyzed. Employment status is one objective indicator of quality of life that has been of particular relevance in the examination of various cardiovascular interventions such as coronary artery bypass surgery. Few studies of heart transplant recipients have specifically focused on return to work, however. In addition to employment status, other objective indicators of quality of life analyzed in subsequent chapters include ability to work, functional impairment, and health status (as measured by sickness impact). The subjective quality of life indicators include overall life satisfaction, patient well-being,

and psychological affect. Chapter 26 is unique in that quality of life is analyzed comparatively: patients on various forms of dialysis and kidney transplant recipients are compared with heart transplant recipients. Moreover, all patients receiving each of the foregoing medical interventions are then compared with the general population of the U.S. in terms of quality of life.

The first conclusion reached in this chapter is simple: survival is not the only indicator of successful medical intervention. Patient quality of life is also important. In short, the quantity versus quality of life tradeoff can no longer be ignored in studies that purport to demonstrate the benefits of surgical procedures such as organ transplants.

A second conclusion reached in this Chapter is that the experiment-therapy dilemma can only be resolved by comparing therapies that are questionable, in this case heart transplantation, with similar therapies that are accepted, in this case renal transplantation and renal dialysis, in terms of what they offer patients with regard to survival and outcomes. If a procedure that is considered experimental has equivalent or better outcomes than accepted therapies, there is little basis for continuing to view the experimental procedure as such.

Perhaps the final implicit conclusion of this Chapter is that quality of life assessment among chronically and terminally ill patients should be the subject of continued research. The tools currently available for such assessments, although adequate, must be considered rudimentary. The methodologies used to make such assessments should also be the subject of further systematic research.

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APPENDIX 23-A

QUALITY OF LIFE QUESTIONS IN THE NATIONAL KIDNEY DIALYSIS AND KIDNEY TRANSPLANTATION STUDY AND THE NATIONAL HEART TRANSPLANTATION STUDY

I. OBJECTIVE QUALITY OF LIFE INDICATORS

A. EMPLOYMENT STATUS

129. What is your CURRENT work activity or employment status?

	(CIRCLE ONE)
EMPLOYED FULL-TIME	01
EMPLOYED PART-TIME	02
EMPLOYED BUT TEMPORARILY LAID OFF	03
UNEMPLOYED, LOOKING FOR WORK	04
UNEMPLOYED, NOT LOOKING FOR WORK	05
UNABLE TO WORK BECAUSE OF HEALTH (DISABLED)	06
HOMEMAKER	07
STUDENT (FULL-TIME)	08
RETIRED	09
OTHER	10

B. ABILITY TO WORK

127. Are you NOW ABLE to work for pay full-time, part-time, or not at all?

	(CIRCLE ONE)
FULL-TIME	01
PART-TIME	02
NOT AT ALL	03

C. FUNCTIONAL ABILITY (KARNOFSKY INDEX)

90. Please check the statement below which best describes this patient's current condition.

	(CIRCLE ONE)
NORMAL: NO COMPLAINTS: NO EVIDENCE OF DISEASE	01
ABLE TO CARRY ON NORMAL ACTIVITY: MINOR SIGNS AND SYMPTOMS OF DISEASE	02
NORMAL ACTIVITY WITH EFFORT: SOME SIGNS AND SYMPTOMS OF DISEASE	03
CARE FOR SELF: UNABLE TO CARRY ON NORMAL ACTIVITY OR DO ACTIVE WORK	04
REQUIRES OCCASIONAL ASSISTANCE BUT IS ABLE TO CARE FOR MOST OF OWN NEEDS	05
REQUIRES CONSIDERABLE ASSISTANCE AND FREQUENT MEDICAL CARE	06
DISABLED: REQUIRES SPECIAL CARE AND ASSISTANCE	07
SEVERELY DISABLED: HOSPITALIZATION IS INDICATED ALTHOUGH DEATH NOT IMMINENT	08
VERY SICK: HOSPITALIZATION NECESSARY	09
MORIBUND: FATAL PROCESSES PROGRESSING RAPIDLY	10

D. HEALTH STATUS (SICKNESS IMPACT PROFILE)

INTRODUCTION TO THE SICKNESS IMPACT PROFILE

To conclude this questionnaire, we would like you to answer a standard set of questions often used to compare groups of people with different health problems. These questions are intended to measure the extent to which sickness has an impact on your ability to do certain activities. Some of the questions may seem quite similar to those you have just answered. However, it is necessary to ask all of the questions to maintain the standardized nature of the Sickness Impact Profile.

We realize that this questionnaire has already taken a considerable amount of your time and effort. We would like you to stop at this point and complete the final part of the questionnaire tomorrow which will take about 20 minutes. Instructions for the Sickness Impact Profile are on the following page.

INSTRUCTIONS

PLEASE READ THE FOLLOWING INTRODUCTION BEFORE YOU READ THE QUESTIONNAIRE. IT IS VERY IMPORTANT THAT EVERYONE COMPLETING THE QUESTIONNAIRE FOLLOWS THE SAME INSTRUCTIONS.

INTRODUCTION TO RESPONDENT

You have certain activities that you do in carrying on your life. Sometimes you do all of these activities. Other times, because of your state of health, you don't do these activities in the usual way: you may cut some out; you may do some for shorter lengths of time; you may do some in different ways. These changes in your activities might be recent or longstanding. We are interested in learning about any changes that describe you today and are related to your state of health.

The questionnaire booklet lists statements that people have told us describe them when they are not completely well. Whether or not you consider yourself sick, there may be some statements that will stand out because they describe you today and are related to your state of health. As you read the questionnaire, think of yourself today. When you read a statement that you are sure describes you and is related to your health, place a check on the line to the right of the statement. For example:

I am not driving my car _____ (026-031)

If you have not been driving for some time because of your health, and are still not driving today, you should respond to this statement.

On the other hand, if you never drive or are not driving today because your car is being repaired, the statement, "I am not driving my car" is not related to your health and you should not check it. If you simply are driving less, or are driving short distances, and feel that the satement only partially describes you, do not check it. In all of these cases you would leave the line to the right of the statement blank. For example:

I am not driving my car _____ (026-031)

Remember that we want you to check this statement only if you are sure it describes you today and is related to your state of health.

Read the introduction to each group of statements and then consider the statements in the order listed. While some of the statements may not apply to you, we ask that you please read all of them. Check those that describe you as you go along. Some of the statements will differ only in a few words, so please read each one carefully. While you may go back to change a response, your first answer is usually the best. Please do not read ahead in the booklet.

Once you have started the questionnaire, it is very important that you complete it within one day (24 hours).

If you find it hard to keep your mind on the statements, take a short break and then continue. When you have read all of the statements on a page, put a check in the BOX in the lower right-hand corner. If you have any questions, please refer back to these instructions.

Please do not discuss the statements with anyone, including family members, while doing the questionnaire.

Now turn to the questionnaire booklet and read the statements. Remember we are interested in the recent or longstanding changes in your activities that are related to your health.

PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

248. I spend much of the day lying down in order to rest _____ (083)

249. I sit during much of the day _____ (049)

250. I am sleeping or dozing most of the time--day and night _____ (104)

251. I lie down more often during the day in order to rest _____ (058)

252. I sit around half-asleep _____ (084)

253. I sleep less at night, for example, wake up too early, don't fall asleep for a long time, awaken frequently _____ (061)

254. I sleep or nap more during the day _____ (060)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE _____

(EB-0705)

PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

255. I say how bad or useless I am, for example, that I am a burden on others _____ (087)

256. I laugh or cry suddenly _____ (068)

257. I often moan and groan in pain or discomfort _____ (069)

258. I have attempted suicide _____ (132)

259. I act nervous or restless _____ (046)

260. I keep rubbing or holding areas of my body that hurt or are uncomfortable _____ (062)

261. I act irritable and impatient with myself, for example, talk badly about myself, swear at myself, blame myself for things that happen _____ (078)

262. I talk about the future in a hopeless way _____ (089)

263. I get sudden frights _____ (074)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE _____

PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

264.	I make difficult moves with help, for example, getting into or out of cars, bathtubs	_____ (084)
265.	I do not move into or out of bed or chair by myself but am moved by a person or mechanical aid	_____ (121)
266.	I stand only for short periods of time	_____ (072)
267.	I do not maintain balance	_____ (098)
268.	I move my hands or fingers with some limitation or difficulty	_____ (064)
269.	I stand up only with someone's help	_____ (100)
270.	I kneel, stoop, or bend down only by holding on to something	_____ (064)
271.	I am in a restricted position all the time	_____ (125)
272.	I am very clumsy in body movements	_____ (068)
273.	I get in and out of bed or chairs by grasping something for support or using a cane or walker	_____ (082)
274.	I stay lying down most of the time	_____ (113)
275.	I change position frequently	_____ (030)
276.	I hold on to something to move myself around in bed	_____ (086)
277.	I do not bathe myself completely, for example, require assistance with bathing	_____ (089)
278.	I do not bathe myself at all, but am bathed by someone else	_____ (115)
279.	I use bedpan with assistance	_____ (114)

280. I have trouble getting shoes, socks, or stockings on _____ (057)

281. I do not have control of my bladder _____ (124)

282. I do not fasten my clothing, for example, require assistance with buttons, zippers, shoelaces _____ (074)

283. I spend most of the time partly undressed or in pajamas _____ (074)

284. I do not have control of my bowels _____ (128)

285. I dress myself, but do so very slowly _____ (043)

286. I get dressed only with someone's help _____ (088)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE _____

THIS GROUP OF STATEMENTS HAS TO DO WITH ANY WORK YOU USUALLY DO IN CARING FOR YOUR HOME OR YARD, CONSIDERING JUST THOSE THINGS THAT YOU DO. PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

287. I do work around the house only for short periods of time or rest often _____ (054)

288. I am doing less of the regular daily work around the house than I would usually do _____ (044)

289. I am not doing any of the regular daily work around the house that I would usually do _____ (086)

290. I am not doing any of the maintenance or repair work that I would usually do in my home or yard _____ (062)

291. I am not doing any of the shopping that I would usually do _____ (071)

292. I am not doing any of the house cleaning that I would usually do _____ (077)

293. I have difficulty doing handwork, for example, turning faucets, using kitchen gadgets, sewing, carpentry _____ (069)

294. I am not doing any of the clothes washing that I would usually do _____ (077)

295. I am not doing heavy work around the house _____ (044)

296. I have given up taking care of personal or household business affairs, for example, paying bills, banking, working on budget. _____ (064)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE _____

(M-0719)

PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

297. I am getting around only within one building _____ (086)

298. I stay within one room _____ (106)

299. I am staying in bed more _____ (081)

300. I am staying in bed most of the time _____ (109)

301. I am not now using public transportation _____ (041)

302. I stay home most of the time _____ (056)

303. I am only going to places with restrooms nearby _____ (056)

304. I am not going into town _____ (048)

305. I stay away from home only for brief periods of time _____ (054)

306. I do not get around in the dark or in unlit places without someone's help _____ (072)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE _____

PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

307.	I am going out less to visit people	_____ (044)
308.	I am not going out to visit people at all	_____ (101)
309.	I show less interest in other people's problems, for example, don't listen when they tell me about their problems, don't offer to help	_____ (067)
310.	I often act irritable toward those around me, for example, snap at people, give sharp answers, criticize easily	_____ (084)
311.	I show less affection	_____ (052)
312.	I am doing fewer social activities with groups of people	_____ (036)
313.	I am cutting down the length of visits with friends	_____ (043)
314.	I am avoiding social visits from others	_____ (080)
315.	My sexual activity is decreased	_____ (051)
316.	I often express concern over what might be happening to my health	_____ (052)
317.	I talk less with those around me	_____ (056)
318.	I make many demands, for example, insist that people do things for me, tell them how to do things	_____ (088)
319.	I stay alone much of the time	_____ (086)
320.	I act disagreeable to family members, for example, I act spiteful, I am stubborn	_____ (088)
321.	I have frequent outbursts of anger at family members, for example, strike at them, scream, throw things at them	_____ (119)
322.	I isolate myself as much as I can from the rest of the family	_____ (102)

323. I am paying less attention to the children _____ (064)

324. I refuse contact with family members, for example, turn away from them _____ (115)

325. I am not doing the things I usually do to take care of my children or family _____ (079)

326. I am not joking with family members as I usually do _____ (043)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE _____

PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

327.	I walk shorter distances or stop to rest often	_____ (048)
328.	I do not walk up or down hills	_____ (056)
329.	I use stairs only with mechanical support, for example, handrail, cane, crutches	_____ (067)
330.	I walk up or down stairs only with assistance from someone else	_____ (076)
331.	I get around in a wheelchair	_____ (096)
332.	I do not walk at all	_____ (105)
333.	I walk by myself but with some difficulty, for example, limp, wobble, stumble, have stiff leg	_____ (055)
334.	I walk only with help from someone	_____ (088)
335.	I go up and down stairs more slowly, for example, one step at a time, stop often	_____ (054)
336.	I do not use stairs at all	_____ (083)
337.	I get around only by using a walker, crutches, cane, walls, or furniture	_____ (079)
338.	I walk more slowly	_____ (035)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE _____

PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

339. I am confused and start several actions at a time _____ (090)

340. I have more minor accidents, for example, drop things, trip and fall, bump into things _____ (075)

341. I react slowly to things that are said or done _____ (059)

342. I do not finish things I start _____ (067)

343. I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things _____ (084)

344. I sometimes behave as if I were confused or disoriented in place or time, for example, where I am, who is around, directions, what day it is _____ (113)

345. I forget a lot, for example, things that happened recently, where I put things, appointments _____ (078)

346. I do not keep my attention on any activity for long _____ (067)

347. I make more mistakes than usual _____ (064)

348. I have difficulty doing activities involving concentration and thinking _____ (080)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE _____

PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

349.	I am having trouble writing or typing	_____ (070)
350.	I communicate mostly by gestures, for example, moving head, pointing, sign language	_____ (102)
351.	My speech is understood only by a few people who know me well	_____ (093)
352.	I often lose control of my voice when I talk, for example, my voice gets louder or softer, trembles, changes unexpectedly	_____ (083)
353.	I don't write except to sign my name	_____ (063)
354.	I carry on a conversation only when very close to the other person or looking at him	_____ (067)
355.	I have difficulty speaking, for example, get stuck, stutter, stammer, slur my words	_____ (076)
356.	I am understood with difficulty	_____ (087)
357.	I do not speak clearly when I am under stress	_____ (064)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE _____

THE NEXT GROUP OF STATEMENTS HAS TO DO WITH ANY WORK YOU USUALLY DO OTHER THAN MANAGING YOUR HOME. BY THIS WE MEAN ANYTHING THAT YOU REGARD AS WORK THAT YOU DO ON A REGULAR BASIS.

DO YOU USUALLY DO WORK OTHER THAN MANAGING YOUR HOME? ____ YES ____ NO

IF YOU ANSWERED YES, GO ON TO THE NEXT PAGE

IF YOU ANSWERED NO:

ARE YOU RETIRED? ____ YES ____ NO

IF YOU ARE RETIRED, WAS YOUR RETIREMENT RELATED TO YOUR HEALTH? ____ YES ____ NO

IF YOU ARE NOT RETIRED, BUT ARE NOT WORKING, IS THIS RELATED TO YOUR HEALTH? ____ YES ____ NO

NOW SKIP THE NEXT PAGE

IF YOU ARE NOT WORKING AND IT IS NOT BECAUSE OF YOUR HEALTH, PLEASE SKIP THIS PAGE

NOW CONSIDER THE WORK YOU DO AND RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH. (IF TODAY IS A SATURDAY OR SUNDAY OR SOME OTHER DAY THAT YOU WOULD USUALLY HAVE OFF, PLEASE RESPOND AS IF TODAY WERE A WORKING DAY.)

358. I am not working at all _____ (361)

(IF YOU CHECKED THIS STATEMENT, SKIP TO THE NEXT PAGE)

359. I am doing part of my job at home _____ (037)

360. I am not accomplishing as much as usual at work _____ (055)

361. I often act irritable toward my work associates, for example, snap at them, give sharp answers, criticize easily _____ (080)

362. I am working shorter hours _____ (043)

363. I am doing only light work _____ (050)

364. I work only for short periods of time or take frequent rests _____ (061)

365. I am working at my usual job but with some changes, for example, using different tools or special aids, trading some tasks with other workers _____ (034)

366. I do not do my job as carefully and accurately as usual _____ (062)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE _____

(RP-0422)

THIS GROUP OF STATEMENTS HAS TO DO WITH ACTIVITIES YOU USUALLY DO IN YOUR FREE TIME. THESE ACTIVITIES ARE THINGS THAT YOU MIGHT DO FOR RELAXATION, TO PASS THE TIME, OR FOR ENTERTAINMENT. PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

367. I do my hobbies and recreation for shorter periods of time _____ (039)

368. I am going out for entertainment less often _____ (036)

369. I am cutting down on some of my usual inactive recreation and pastimes, for example, watching TV, playing cards, reading _____ (059

370. I am not doing any of my usual inactive recreation and pastimes, for example, watching TV, playing cards, reading _____ (084)

371. I am doing more inactive pastimes in place of my other usual activities _____ (051)

372. I am doing fewer community activities _____ (033)

373. I am cutting down on some of my usual physical recreation or activities _____ (043)

374. I am not doing any of my usual physical recreation or activities _____ (077)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE _____

PLEASE RESPOND TO ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

375.	I am eating much less than usual	_____	(037)
376.	I feed myself but only by using specially prepared food or utensils	_____	(077)
377.	I am eating special or different food, for example, soft food, bland diet, low-salt, low-fat, low-sugar	_____	(043)
378.	I eat no food at all but am taking fluids	_____	(104)
379.	I just pick or nibble at my food	_____	(059)
380.	I am drinking less fluids	_____	(036)
381.	I feed myself with help from someone else	_____	(099)
382.	I do not feed myself at all, but must be fed	_____	(117)
383.	I am eating no food at all, nutrition is taken through tubes or intravenous fluids	_____	(133)

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE _____

II. SUBJECTIVE QUALITY OF LIFE INDICATORS

A. GENERAL WELL-BEING INDEX (GWB)
(Fazio, 1977)

21. Now we would like you to answer a few questions about how you have felt and about how things have been within the PAST MONTH. How have you been feeling in general during the PAST MONTH?

IN EXCELLENT SPIRITS	01
IN VERY GOOD SPIRITS	02
IN GOOD SPIRITS MOSTLY	03
UP AND DOWN IN SPIRITS A LOT	04
IN LOW SPIRITS MOSTLY	05
IN VERY LOW SPIRITS	06

22. Have you been bothered by nervousness or your nerves during the PAST MONTH?

EXTREMELY SO--TO THE POINT WHERE YOU COULD NOT WORK OR TAKE CARE OF THINGS	01
VERY MUCH SO	02
QUITE A BIT	03
SOME--ENOUGH TO BE BOTHERED	04
A LITTLE	05
NOT AT ALL	06

23. Have you been in firm control of your behavior, thoughts, emotions, OR feelings during the PAST MONTH?

YES, DEFINITELY SO	01
YES, FOR THE MOST PART	02
GENERALLY SO	03
NOT TOO WELL	04
NO, ENOUGH TO BOTHER YOU SOMEWHAT	05
NO, ENOUGH TO BOTHER YOU VERY MUCH	06

24. Have you felt so sad, discouraged, hopeless or had so many problems that you wondered if anything was worthwhile during the PAST MONTH?

EXTREMELY SO--TO THE POINT THAT YOU HAVE JUST ABOUT GIVEN UP	01
VERY MUCH SO	02
QUITE A BIT	03
SOME--ENOUGH TO BE BOTHERED	04
A LITTLE BIT	05
NOT AT ALL	06

25. Have you been under or felt you were under any strain, stress, or pressure during the PAST MONTH?

YES--ALMOST MORE PRESSURE THAN YOU COULD BEAR OR STAND	01
YES--QUITE A BIT OF PRESSURE	02
YES--SOME - MORE THAN USUAL	03
YES--SOME - BUT ABOUT USUAL	04
YES--A LITTLE	05
NOT AT ALL	06

26. How happy, satisfied, or pleased have you been with your personal life during the PAST MONTH?

EXTREMELY HAPPY--COULD NOT HAVE BEEN MORE SATISFIED OR PLEASED	01
VERY HAPPY	02
FAIRLY HAPPY	03
SATISFIED--PLEASED	04
SOMEWHAT DISSATISFIED	05
VERY DISSATISFIED	06

27. Have you had any reason to wonder if you were losing your mind, or losing control over the way you act, talk, think, feel, or of your memory during the PAST MONTH?

NOT AT ALL	01
ONLY A LITTLE	02
SOME--BUT NOT ENOUGH TO BE CONCERNED OR WORRIED ABOUT	03
SOME AND A LITTLE CONCERNED ABOUT IT	04
SOME AND QUITE CONCERNED ABOUT IT	05
YES, VERY MUCH SO AND VERY CONCERNED ABOUT IT	06

28. Have you been anxious, worried, or upset during the PAST MONTH?

EXTREMELY SO--TO THE POINT OF BEING SICK OR ALMOST SICK	01
VERY MUCH SO	02
QUITE A BIT	03
SOME--ENOUGH TO BE BOTHERED	04
A LITTLE BIT	05
NOT AT ALL	06

29. Have you felt down-hearted and blue during the PAST MONTH?

ALL OF THE TIME	01
MOST OF THE TIME	02
A GOOD BIT OF THE TIME	03
SOME OF THE TIME	04
A LITTLE OF THE TIME	05
NONE OF THE TIME	06

30. Have you been feeling emotionally stable and sure of yourself during the PAST MONTH?

ALL OF THE TIME	01
MOST OF THE TIME	02
A GOOD BIT OF THE TIME	03
SOME OF THE TIME	04
A LITTLE OF THE TIME	05
NONE OF THE TIME	06

CONSTRUCTION OF THE GENERAL WELL-BEING INDEX (GWB);

(1) Questions 21, 23, 26, 27, and 30 are recoded as follows: (6=1)(5=2)(4=3)=(3=4)(2=5)(1=6). By reverse scoring these, a high score on the scale will indicate high well-being while a low score will indicate low well-being.

(2) The responses for each individual are summed across all ten items resulting in a score ranging from 10 to 60.

(3) The mean score of each individual is obtained by dividing each individual's total score by 10. Thus, average scores can range from 1.0 to 6.0, where a score of 1.0 indicates low well-being and a score of 6.0 high well-being.

(4) Mean scores are then computed for all patients.

B. INDEX OF PSYCHOLOGICAL AFFECT (IPA)
(Campbell et al., 1976; 45-49)

45. Here are some words and phrases which we would like you to use to describe how you feel about your present life. For example, if you think your present life is very "boring," put an X in the box right next to the word "boring." If you think it is very "interesting," put an X in the box right next to the word "interesting." If you think it is somewhere in between, put an X where you think it belongs. Put an X in one box on every line.

A.	BORING	1	2	3	4	5	6	7	INTERESTING
B.	ENJOYABLE	1	2	3	4	5	6	7	MISERABLE
C.	EASY	1	2	3	4	5	6	7	HARD
D.	USELESS	1	2	3	4	5	6	7	WORTHWHILE
E.	FRIENDLY	1	2	3	4	5	6	7	LONELY
F.	FULL	1	2	3	4	5	6	7	EMPTY
G.	DISCOURAGING	1	2	3	4	5	6	7	HOPEFUL
H.	TIED DOWN	1	2	3	4	5	6	7	FREE
I.	DISAPPOINTING	1	2	3	4	5	6	7	REWARDING
J.	BRINGS OUT THE BEST IN ME	1	2	3	4	5	6	7	DOESN'T GIVE ME MUCH CHANCE

NOTE: On the actual questionnaire the numbers in the boxes do not appear.

CONSTRUCTION OF THE INDEX OF PSYCHOLOGICAL AFFECT (IPA);

(1) Questions 45B, 45E, 45F, and 45J are recoded as follows: (1=7)(2=6)(3=5)(4=4)(5=3)(6=2)(7=1).

(2) Question 45C and 45H are dropped from the scale.

(3) The responses for each individual are summed resulting in a score ranging from 8 to 56.

(4) The mean score of each individual is obtained by dividing each individual's total score by 8. Thus, average scores can range from 1.0 to 7.0, where a score of 1.0 indicates negative affect and a score of 7.0 positive affect.

C. OVERALL LIFE SATISFACTION (OLS)
(Campbell et al., 1976:32-38).

40. How satisfied are you with your life as a whole these days?

SCORING OF ITEM.

(1) Responses are recoded as follows: (1=7)(2=6)(3=5)(4=4)(5=3)(6=2)(7=1).

(2) Mean scores are then computed for all patients. Raw scores can fall between 1 and 7.

D. INDEX OF WELL-BEING (IWB)
(Campbell et al., 1976:49-57)

CONSTRUCTION OF INDEX OF WELL-BEING (IWB);

This variable is based on two previous measures, the patient's overall life satisfaction (see C above) and Index of Psychological Affect (see B above). The IWB is computed according to the following formula:

IWB = 1.1 (OLS) + 1.0 (IPA)

Scores can range between 2.1 and 14.7 where a score of 2.1 indicates low well-being and a score of 14.7 high well-being.

Mean scores are then computed for all patients.

E. POSITIVE AFFECT SCALE (PAS)
(Bradburn, 1969:58)

20. We are also interested in the way you are feeling these days. During the PAST FEW WEEKS, did you ever feel....

		YES	NO
A.	PARTICULARLY EXCITED OR INTERESTED IN SOMETHING?	01	02
B.	SO RESTLESS THAT YOU COULDN'T SIT LONG IN A CHAIR?	01	02
C.	PROUD BECAUSE SOMEONE COMPLIMENTED YOU ON SOMETHING YOU HAD DONE?	01	02
D.	VERY LONELY OR REMOTE FROM OTHER PEOPLE?	01	02
E.	PLEASED ABOUT HAVING ACCOMPLISHED SOMETHING?	01	02
F.	BORED?	01	02
G.	ON TOP OF THE WORLD?	01	02
H.	DEPRESSED OR VERY UNHAPPY?	01	02
I.	THAT THINGS WERE GOING YOUR WAY?	01	02
J.	UPSET BECAUSE SOMEONE CRITICIZED YOU?	01	02

CONSTRUCTION OF POSITIVE AFFECT SCALE (PAS);

(1) The Positive Affect Scale is based on a subset of items contained in the above question, including items A, C, E, G, and I.

(2) These items are recoded such that 01 = 1 and 02 = 0.

(3) The PAS score is derived by adding each individual's response to these items with scores ranging between 0 and 5. The person's score indicates the number of positive feelings they have had.

(4) A mean score is then computed for all patients.

F. NEGATIVE AFFECT SCALE (NAS)
(Bradburn, 1969:58)

CONSTRUCTION OF THE NEGATIVE AFFECT SCALE (NAS);

(1) The Negative Affect Scale is based on a subset of items contained in question 20, above, including items B, D, F, H, and J.

(2) These items are recoded such that 01 = 1 and 02 = 0.

(3) The NAS score is derived by adding each individual's response to these five items with scores ranging between 0 and 5. The person's score indicates the number of negative feelings they have had.

(4) A mean score is then computed for all patients.

G. AFFECT BALANCE SCALE (ABSCALE)
(Bradburn, 1969:59)

CONSTRUCTION OF THE AFFECT BALANCE SCALE (ABSCALE);

(1) The Affect Balance Scale is based on both the PAS and the NAS. All items contained in Question 20 (above) are used to construct the scale.

(2) The PAS is recoded as follows: (1=0)(2=1)(3=2)(4=3)(5=4)

(3) A score of 5 on the NAS is recoded to 4 (i.e., 5 = 4).

(4) The ABSCALE is computed as follows: ABSCALE = (PAS - NAS) + 5.

(5) A mean score is then computed for all patients.

(6) To summarize, we first combine scores of 0 and 1 on the PAS and of 4 and 5 on the NAS, which results in a range of scores from 0 to 4 on each scale. We then subtract each individual's score on the NAS from their score on the PAS, yielding a distribution of scores running from -4 to +4. For computation purposes, a constant of +5 is added to each sum, giving a scale with values of +1 to +9. A mean score is then computed for all patients.

H. GENERAL LIFE SATISFACTION (GENSAT)
(Campbell et al., 1976)

31. Some people feel they can run their lives pretty much the way they want to; others feel the problems of life are sometimes too big for them. Which one are you most like?

    CAN RUN OWN LIFE 01

    PROBLEMS OF LIFE TOO BIG 02

32. Up to now, have you been able to satisfy most of your ambitions in life or have you had to settle for less than you hoped for?

    SATISFIED MOST AMBITIONS 01

    HAVE HAD TO SETTLE FOR LESS 02

33. Do you think you have had a fair opportunity to make the most of yourself or life, or have you been held back in some ways?

    HAVE HAD A FAIR OPPORTUNITY 01

    HAVE BEEN HELD BACK 02

CONSTRUCTION OF THE GENERAL LIFE SATISFACTION MEASURE (GENSAT);

(1) The GENSAT measure is based on the above three questions. It is simply a cumulative scale.

(2) The items are recoded so that 01 = 2 and 02 = 1.

(3) The individual's responses to these three items are totaled with scores ranging between 3 and 6.

(4) The individual's total score is then divided by 3 producing a mean score ranging between 1.0 and 2.0.

(5) Mean scores are then computed for all patients.

I. SATISFACTION WITH MARRIAGE
(Campbell et al., 1976)

42. (FOR MARRIED OR SEPARATED PATIENTS ONLY) How satisfied are you with your marriage?

COMPLETELY SATISFIED								COMPLETELY DISSATISFIED
	1	2	3	4	5	6	7	

SCORING OF THE ITEM;

(1) Responses are recoded as follows: (1=7)(2=6)(3=5)(4=4)(5=3)(6=2)(7=1).

(2) Mean scores are then computed for all patients. Raw scores can fall between 1 and 7.

J. SATISFACTION WITH SEX LIFE
(Campbell et al., 1976)

69. How satisfied are you with your sexual relationship(s) now?

COMPLETELY SATISFIED								COMPLETELY DISSATISFIED
	1	2	3	4	5	6	7	

SCORING OF THE ITEM;

(1) Responses are recoded as follows: (1=7)(2=6)(3=5)(4=4)(5=3)(6=2)(7=1).

(2) Mean scores are then computed for all patients. Raw scores can fall between 1 and 7.

K. SATISFACTION WITH FAMILY LIFE
(Campbell et al., 1976)

41. All things considered, how satisfied are you with your family life--the time you spend and the things you do with members of your family?

COMPLETELY SATISFIED								COMPLETELY DISSATISFIED
	1	2	3	4	5	6	7	

SCORING OF THE ITEM;

(1) Responses are recoded as follows: (1=7)(2=6)(3=5)(4=4)(5=3)(6=2)(7=1).

(2) Mean scores are then computed for all patients. Raw scores can fall between 1 and 7.

L. SATISFACTION WITH SAVINGS AND INVESTMENTS
(Campbell et al., 1976)

43. How satisfied are you with your family's situation so far as savings and investments are concerned?

COMPLETELY SATISFIED								COMPLETELY DISSATISFIED
	1	2	3	4	5	6	7	

M. SATISFACTION WITH STANDARD OF LIVING
(Campbell et al., 1976)

38. The things people have--housing, car, furniture, recreation, and the like--make up their standard of living. Some people are satisfied with their standard of living, others feel it is not as high as they would like. How satisfied are you with your standard of living?

COMPLETELY SATISFIED	1	2	3	4	5	6	7	COMPLETELY DISSATISFIED

SCORING OF THE ITEM;

(1) Responses are recoded as follows: (1=7)(2=6)(3=5)(4=4)(5=3)(6=2)(7=1).

(2) Mean scores are then computed for all patients. Raw scores can fall between 1 and 7.

N. SATISFACTION WITH FRIENDSHIPS
(Campbell et al., 1976)

83. All things considered, how would you rate your friendships--the time you spend with friends, the things you do together, the number of friends you have, as well as the particular people who are your friends?

COMPLETELY SATISFIED	1	2	3	4	5	6	7	COMPLETELY DISSATISFIED

SCORING OF THE ITEM;

(1) Responses are recoded as follows: (1=7)(2=6)(3=5)(4=4)(5=3)(6=2)(7=1).

(2) Mean scores are then computed for all patients. Raw scores can fall between 1 and 7.

O. SATISFACTION WITH HEALTH

44. Most people get sick now and then, and others, such as yourself, have chronic illnesses. Overall, how satisfied are you with your health at this time? Are you...

COMPLETELY SATISFIED	01
VERY SATISFIED	02
SATISFIED	03
NEUTRAL	04
DISSATISFIED	05
VERY DISSATISFIED	06
COMPLETELY DISSATISFIED	07

SCORING OF THE ITEM;

(1) The responses to this question are recoded in a positive direction (e.g., 05 = 1, 04 = 2, 03 = 3, 02 = 4, and 05 = 1).

(2) Mean scores are then computed for all patients. Raw scores can fall between 1 and 7.

P. FEELING ABOUT PRESENT LIFE (EASY VERSUS HARD)
(Campbell et al., 1976)

45C

EASY [1] [2] [3] [4] [5] [6] [7] HARD

SCORING OF THIS ITEM;

(1) Responses are recoded as follows: (1=7)(2=6)(3=5)(4=4)(5=3)(6=2)(7=1).

(2) Mean scores are then computed for all patients. Raw scores can fall between 1 and 7.

Q. FEELING ABOUT PRESENT LIFE (FREE, TIED DOWN)
(Campbell et al., 1976)

45H.

TIED DOWN [1] [2] [3] [4] [5] [6] [7] FREE

SCORING OF THIS ITEM:

(1) Mean scores are computed for all patients. Raw scores can fall between 1 and 7.

R. MISCELLANEOUS INDICATORS OF QUALITY OF LIFE

34. Compared to OTHER PEOPLE YOU KNOW, would you say that you have enjoyed your life up to now more than most people, about the same, or less than most people?

MORE 01

ABOUT THE SAME 02

LESS 03

35. Taking all things together, how would you say things are these days--would you say you're very happy, pretty happy, or not too happy these days?

VERY HAPPY 01

PRETTY HAPPY 02

NOT TOO HAPPY 03

36. If you were to compare your quality of life with that of OTHER PEOPLE WHOM YOU KNOW, would you say your quality of life is better than theirs, about the same, or lower than theirs?

BETTER 01

ABOUT THE SAME 02

LOWER 03

37. Comparing your health with that of OTHER PEOPLE YOUR AGE, would you say your health is better than theirs, about the same, or poorer than theirs?

BETTER 01

ABOUT THE SAME 02

POORER 03

CHAPTER 24

THE WORK STATUS OF LIVING HEART TRANSPLANT RECIPIENTS

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A. INTRODUCTION

As noted in Chapter 23, the quality of life of an individual undergoing various types of medical intervention, such as heart transplantation, only becomes a concern when the intervention is demonstrated to have life-saving value, not merely therapeutic potential. Upon the demonstration of life-saving value, attention clearly shifts from quantity of life to quality of life. Although patient survival may continue to improve over time, as it has for heart transplantation, the quality of life associated with the intervention may be uneven. For example, a patient may initially be overwhelmed with the fact that they have a "new lease on life" afforded by transplantation, but following this initial "honeymoon" period, the patient may begin to realize and question the long-term implications of the treatment regimen necessitated by transplantation. Thus, the patient may reconsider the merits of the therapy they have received. This response to successful intervention has been observed among end-stage renal disease patients undergoing maintenance dialysis. Reichsman and Levy (1972) report that dialysis patients are initially elated with their new therapy, since dialysis makes them feel considerably better than they did at the last stages of kidney failure. This period of exhilaration, however, is short-lived, lasting from 6 weeks to 6 months, and is followed by a period of disenchantment and discouragement (Simmons, 1978).

For many people who have survived a terminal disease or who have learned to cope with chronic illness, their ability to work and participate in the labor force is often a primary consideration. If a

person has been forced to quit work because of their health, they often look forward to medical treatment that will enable them to return to their primary activity. For homemakers the concerns are similar. Will successful medical intervention enable them to go about their usual activities of raising and caring for their family? Mothers, for example, are concerned about how their children will perceive their illness and the limitations it imposes (Evans, 1978; Friedlander and Viederman, 1982; Rutter, 1966). Working fathers are similarly concerned. At times a role reversal occurs such as when a mother or wife becomes the major breadwinner as the father/husband is forced to quit work. How easily and readily does adaptation occur? Is the father/husband threatened by this situation?

Work is an integral part of the human condition, one with which people identify strongly. Campbell et al. (1976:237) in their treatise, The Quality of American Life, emphasize the importance of work as follows:

> Productive work is a major domain of life to almost all adult Americans, both those who work for pay and those who work in the home. Except for persons still preparing themselves for a career or retired from a life of work, very few Americans are not in some degree involved in the world of work. Work is not only a virtually ubiquitous personal experience, it is also a domain of intense public concern, the subject of many corporate and governmental programs intended to increase the availability of jobs and the quality of work life.

A stronger view on the importance of work has been offered by Katherine Mansfield. As she was dying of tuberculosis, the well-known English short-story writer noted in the last pages of her journal that "Work is more important than life."

In their analysis, Campbell et al. (1976) found work to be a strong predictor of overall quality of life. Their findings with regard to unemployment and retirement are clearly important. They summarize their results as follows (Campbell et al., 1976:318):

> Unemployment appears to have substantial deleterious effects on the overall quality of life. For man, at least, this is not mostly because of the consequent loss of income, but because of the effects of job loss on how the individual perceives himself and his society. Retirement appears to resemble unemployment in certain respects, since for many people it is more an involuntary transition than a deliberate choice. Health problems and age-linked stereotypes combine to induce retirement at an earlier age than many persons would have preferred, at least retrospectively. Furthermore, retired persons appear to be somewhat less satisfied with their lives than are comparable persons who are still working. Among the retired, better adjustment is found among those who have remained engaged in other social roles.

Many heart transplant recipients have been forced to withdraw from the labor force prematurely. Some have retired, but the majority of those not working are unable to do so because of their health.

In this chapter, we examine the employment status of heart transplant recipients in considerable detail. We begin with a gross categorization of the kind of work (occupations) in which patients are now engaged as well as those in which they were engaged immediately prior to their transplant. We next examine their pre- and post-transplant employment status. To provide some perspective on the subject of employment, heart transplant recipients are compared with patients who participated in the Coronary Artery Surgery Study (CASS) as well as kidney transplant recipients and patients on kidney dialysis who participated in the National Kidney Dialysis and Kidney

Transplantatio Study. Finally, the analyses focus on employed patients in an effort to determine what, if anything, employers have done to assist patients who are currently working.

B. OCCUPATIONS OF HEART TRANSPLANT RECIPIENTS

Occupations have been coded according to the U.S. Bureau of the Census classification originally developed by Blau and Duncan (1967; Reiss, 1961:109-161). The classification system allows for a very specific recording of the respondent's occupations which can then be recoded into a much broader classification. A complete listing of occupations used in this study is included as Appendix 24-A. For purposes of this analysis the most general categorization of occupations is utilized. Table 24-1 presents these data for all living heart transplant recipients and for those recipients who are currently working.

As shown in Table 24-1, the vast majority of heart transplant recipients have been employed in a white collar occupation. Prior to their heart transplant, 46.0 percent of the patients were either professional and technical workers or managers and administrators. At the present time, of the working patients, 66.0 percent are employed in these same occupations. While their occupations may hold some epidemiological significance, that is, people in these occupations may be more likely to encounter cardiovascular disease disproportionate to the population, it is also true that such occupations may greatly facilitate return to work. As shown in Table 24-1, laborers are much less likely to return to work than are professionals and managers.

Table 24-1
Occupational Data For Heart Transplant Recipients

OCCUPATIONAL CATEGORY	PRETRANSPLANT OCCUPATION (BOTH WORKING AND NONWORKING PATIENTS) NUMBER	PERCENT	CURRENT OCCUPATION (WORKING PATIENTS ONLY) NUMBER	PERCENT*
Professional and Technical Workers	33	23.7	21	39.6
Managers and Administrators, Except Farm	31	22.3	14	26.4
Sales Workers	11	7.9	2	3.8
Clerical and Kindred Workers	5	3.6	7	13.2
Craftsmen and Kindred Workers	25	18.0	3	5.7
Operators, Except Transport	11	7.9	2	3.8
Transport Equipment Operators	4	6.5	0	0.0
Laborers, Except Farm	9	6.5	0	0.0
Farmers and Farm Managers	2	1.4	1	1.9
Farm Laborers and Farm Foremen	0	0.0	0	0.0
Service Workers, Except Private Household	8	5.8	3	5.7
Private Household Workers	0	0.0	0	0.0
TOTAL	139	100.0	53	100.1

*Total may not equal 100.0 percent due to rounding error.

C. EMPLOYMENT STATUS

1. PRETRANSPLANT EMPLOYMENT STATUS

All patients were asked to indicate their employment status during the year prior to their heart transplant. At the outset of the study it was recognized that many patients could have been debilitated by heart disease during the year prior to their transplant. In fact, it is quite possible that many patients may have been unable to work for more than one year prior to their transplant. Nonetheless, the focus of attention here is on the year prior to the transplant.

As shown in Table 24-2, 46.1 percent of the patients (N = 70) were working full-time, and another 9.2 percent (N = 14) were working part-time. Thus, 55.3 percent of the living heart transplant recipients were working during the year prior to their transplant. Fully, one-third of the patients were unable to work because of their health and, therefore, considered themselves disabled. Only 3.3 percent of the patients were homemakers, 5.3 percent were full-time students, and 2.6 percent were retired. It is not surprising that such a low percentage of patients were retired given the age limitation imposed on the selection of heart transplant candidates. Because of health, persons over the age of 55 years are generally not considered as heart transplant candidates.

An examination of the medical records of all heart transplant recipients (living and deceased) at the transplant centers participating in the study yields a slightly different historical view of the employment status of the patients. Each participating center was asked to indicate what, historically, had been the employment status

Table 24-2
Employment Status of Living Heart Transplant Recipients
During The Year Prior To Their Heart Transplant

EMPLOYMENT STATUS	NUMBER OF PATIENTS	PERCENT OF PATIENTS
Employed Full-Time	70	46.1
Employed Part-Time	14	9.2
Employed But Temporarily Laid Off	0	0.0
Unemployed, Looking For Work	0	0.0
Unemployed, Not Looking For Work	0	0.0
Unable To Work Because of Health (Disabled)	51	33.6
Homemaker	5	3.3
Student (Full-Time)	8	5.3
Retired	4	2.6
Other	0	0.0

of each patient. Although such data were unavailable for 18 patients, the results presented in Table 24-3 reveals that nearly 80 percent of the patients had been employed full-time in the past. In fact, only 3.8 percent of the patients were characterized, historically, as being unable to work because of their health. Nearly 12 percent were full-time students.

Still another view of heart transplant recipients is offered by an examination of patient medical records to ascertain each patient's employment status at the time of evaluation. Table 24-4, displays these results. As shown here, of the 430 patients for whom these data were available, only 6.7 percent were working full-time, while 80.7 percent of them were unable to work because of their health. Given the condition of most patients at the time of evaluation, these results are not surprising.

2. CURRENT EMPLOYMENT STATUS

Before being asked about their current employment status, all patients were asked a series of questions concerning their ability to work. In response to an initial question on ability to work, 57.2 percent (N = 87) of the patients indicated that they were unable to work for pay, 64 patients (42.1 percent) indicated that they were able to work for pay, and one patient indicated that he did not know. Thus, approximately the same fraction of patients who were working prior to their transplant (55.3 percent) indicate that they are now unable to work on a job (57.2 percent).

Patients were next asked about the kind and amount of work they may be able to do. Once again, this question was asked of all

Table 24-3
Employment Status, Historically, of All Heart Transplant Recipients

EMPLOYMENT STATUS	NUMBER OF PATIENTS	PERCENT OF PATIENTS
Employed Full-Time	331	78.3
Employed Part-Time	5	1.2
Employed But Temporarily Laid Off	0	0.0
Unemployed, Looking For Work	0	0.0
Unemployed, Not Looking For Work	1	.2
Unable To Work Because of Health (Disabled)	16	3.8
Homemaker	20	4.7
Student (Full-Time)	49	11.6
Retired	0	0.0
Other	1	.2

Number of missing cases = 18

Table 24-4
Employment Status of All Heart Transplant Recipients At The Time of Evaluation For Heart Transplantation

EMPLOYMENT STATUS	NUMBER OF PATIENTS	PERCENT OF PATIENTS
Employed Full-Time	29	6.7
Employed Part-Time	6	1.4
Employed But Temporarily Laid Off	2	.5
Unemployed, Looking For Work	0	0.0
Unemployed, Not Looking For Work	3	0.7
Unable To Work Because of Health (Disabled)	348	80.7
Homemaker	13	3.0
Student (Full-Time)	15	3.5
Retired	12	2.8
Other	3	.7

Number of missing cases = 10

patients regardless of their response to the preceding question about ability to work for pay. In answering this question, 73.7 percent (N = 112) of the patients indicated that they were limited in the kind of work for pay that they could do. When asked about the amount of work for pay they could do, 67.8 percent (N = 103) of the patients noted that there was a limit in the amount of work they could do.

The next two questions asked of the patients concerned how frequently they were able to work. Here again, the questions were asked of all respondents. Of the patients responding, 33.6 percent said they could work full-time and 24.3 percent said part-time. The remaining 64 patients either could not work at all, or were uncertain if they were able to do so. Finally, of the patients who were able to work, 57 (37.5 percent) said they could work regularly, while 32 (21.1 percent) said they could only work occasionally or irregularly.

All patients were finally asked to characterize their current employment status using the same categories they used to indicate their pretransplant employment status. The results are shown in Table 24-5. As indicated, 77 patients (50.7 percent) were unable to work because of their health, 25.0 percent were working full-time, 6.6 percent part-time, 3.9 percent were unemployed but looking for work, 3.3 percent remained homemakers, 2.0 percent were full-time students, and 7.9 percent had retired. One patient described his employment status as "other."

Table 24-6 shows the pre- and posttransplant employment status of all living heart transplant recipients. Clearly, a much larger fraction of patients now considered themselves disabled than

Table 24-5
Current Employment Status of Living Heart Transplant Recipients

EMPLOYMENT STATUS	NUMBER OF PATIENTS	PERCENT OF PATIENTS
Employed Full-Time	38	25.0
Employed Part-Time	10	6.6
Employed But Temporarily Laid Off	0	0.0
Unemployed, Looking For Work	6	3.9
Unemployed, Not Looking For Work	0	0.0
Unable To Work Because of Health (Disabled)	77	50.7
Homemaker	5	3.3
Student (Full-Time)	3	2.0
Retired	12	7.9
Other	1	0.7

Table 24-6
Pre- and Posttransplant Employment Status of Living
Heart Transplant Recipients
(Expressed as a Percent)

EMPLOYMENT STATUS	DURING YEAR PRIOR TO TRANSPLANT	POST-TRANSPLANT
Employed Full-Time	46.1	25.0
Employed Part-Time	9.2	6.6
Employed But Temporarily Laid Off	0.0	0.0
Unemployed, Looking For Work	0.0	3.9
Unemployed, Not Looking For Work	0.0	0.0
Unable To Work Because of Health (Disabled)	33.6	50.7
Homemaker	3.3	3.3
Student (Full-Time)	5.3	2.0
Retired	2.6	7.9
Other	0.0	0.7

did during the year prior to their transplant. A few more patients have retired. Most surprising, however, given reports published in the literature, is that 23.7 percent fewer patients are working now than were working during the year prior to their transplant (Christopherson et al., 1976; Christopherson, 1982; English et al., 1980; 1983).

Table 24-7 summarizes the employment status of heart transplant recipients at each of the time periods described above. Clearly, patients were most debilitated at the time of their evaluation (80.7 percent). Historically, however, most patients were employed full-time (79.5 percent). During the year prior to their transplant, however, only 55.3 percent of the patients were working full or part-time, and at the present time this proportion has further dropped to 31.6 percent. Nonetheless, it appears that a larger percentage of patients feel they are able to work since 57.9 percent of the living patients said they could work either full-time or part-time. As shown in Table 24-8, 33.6 percent of the patients said they were able to work full-time but only 25.0 percent were. In addition, 24.3 percent of the patients said they were able to work part-time but only 6.6 percent were actually working part-time.

3. JOB SATISFACTION

Work is clearly one of the most important domains of life. While a major reason for working is, of course, financial, Campbell and associates (1976:318) found that a high proportion of those in the general population who work say they would work even if they had all the money they wanted. Job satisfaction, however, must be considered

Table 24-7
Employment Status of Heart Transplant Recipients
At Different Time Periods
(Expressed as a Percent)

EMPLOYMENT STATUS	WORK STATUS HISTORICALLY[1]	DURING YEAR PRIOR TO TRANSPLANT[2]	AT TIME OF EVALUATION[1]	CURRENT WORK STATUS[2]
Employed Full-Time	78.3	46.1	6.7	25.0
Employed Part-Time	1.2	9.2	1.4	6.6
Employed But Temporarily Laid Off	0.0	0.0	0.5	0.0
Unemployed, Looking For Work	0.0	0.0	0.0	3.9
Unemployed, Not Looking For Work	0.2	0.0	0.7	0.0
Unable To Work Because of Health (Disabled)	3.8	33.6	80.7	50.7
Homemaker	4.7	3.3	3.0	3.3
Student (Full-Time)	11.6	5.3	3.5	2.0
Retired	0.0	2.6	2.8	7.9
Other	0.2	0.0	0.7	0.7

[1]All heart transplant recipients.

[2]Only living heart transplant recipients.

Table 24-8
Percentage of Patients Working and Able to Work

EMPLOYMENT STATUS	ABLE TO WORK	ACTUALLY WORKING
Work Full-Time	33.6	25.0
Work Part-Time	24.3	6.6
TOTAL	57.9	31.6

an important determinant of the propensity to work. In an effort to gain a better perspective on work, all working living heart transplant recipients were asked about job satisfaction. The results are interesting, particularly when compared with job satisfaction levels in the general population. The results of our simple descriptive analysis of job satisfaction are presented in Table 24-9. Clearly, heart transplant recipients are remarkably similar to the general population with regard to job satisfaction, despite the fact that their health has been seriously jeopardized and, to some extent, remains compromised.

4. EMPLOYER ASSISTANCE

Some employers make special attempts to accomodate workers who are ill or handicapped in an effort to enable them to continue to work, even though they may be unable to work at the same pace or the same job. For this reason, and the expectation that not all employers make an effort to retain employees when they become ill or debilitated, we asked all working heart transplant recipients if their employer had done "...anything special for you because of your heart condition to make it easier for you to work at your job?" Of the 46 working patients who responded to this question, 15 or 32.6 percent indicated that their employer had provided them with some assistance to make their job easier. Table 24-10 shows the percentage of patients who received various kinds of assistance.

Table 24-9
Job Satisfaction Among Heart Transplant Recipients
That Are Currently Working
(Expressed as a Percent)

LEVEL OF SATISFACTION	HEART TRANSPLANT RECIPIENTS	GENERAL[1] POPULATION
Completely Satisfied	35.4	36.0
Very Satisfied	29.2	30.0
Satisfied	22.9	13.0
Neutral	6.0	13.0
Dissatisfied	4.2	4.0
Very Dissatisfied	2.1	2.0
Completely Dissatisfied	0.0	2.0

[1]Source: Campbell et al., 1976.

Table 24-10
Types of Assistance Offered to Heart Transplant Recipients By Their Employers

TYPE OF ASSISTANCE	NUMBER OF PATIENTS	PERCENT OF PATIENTS
Got Someone To Help You	3	20.0
Changed Jobs (Tasks) To Something You Could Do	9	60.0
Helped You Learn New Skills	2	13.3
Shortened Work Day	6	40.0
Allowed Flexible Schedule	8	53.3
Allowed More Breaks and Rest Periods	7	46.7
Got Special Equipment For The Job	0	0.0
Arranged Special Transportation	0	0.0
Extended Sick Leave	4	26.7
Other	1	6.7

D. COMPARISONS WITH THE CORONARY ARTERY SURGERY STUDY (CASS)

As noted in the introduction to this Chapter, it is possible to compare the employment status of the living heart transplant recipients with that of the patients who participated in the Coronary Artery Surgery Study. Before doing so, however, a brief overview of the CASS is provided. The study description is taken from a recent publication by the CASS Principal Investigators and their associates (1983:951-952).

1. DESCRIPTION OF THE CASS DATA

The CASS is a prospective randomized study designed to compare the results of medical and surgical treatment in subsets of patients with anatomically proved coronary artery disease. The study consists of a registry of 24,959 consecutive patients who underwent coronary arteriography at 15 cooperating clinical sites in the United States and Canada between 1974 and 1979. From this registry, 780 consecutive patients with greater than or equal to 70 percent stenosis of one or more operable vessels were randomly assigned to medical and surgical treatment at 11 participating sites (Principal Investigators of CASS and their associates, 1983).

The 780 study patients were prospectively divided into the three following clinical subsets: (1) group A, patients with mild angina (Canadian Heart Association Class I or II) and normal left ventricular function (N = 514 patients or 66 percent of total); (2) group B, patients with mild angina and improved left ventricular function (N = 106 patients or 14 percent of total); and (3) group C,

patients who were free of angina after myocardial infarction (N = 160 patients or 20 percent of total).

After randomization all patients were managed medically by their referring physicians. Guidelines were provided by the CASS Steering Committee for the treatment of angina pectoris, arrhythmias, and congestive heart failure for management of risk factors. Patients randomly assigned to surgical therapy underwent coronary revascularization with a mean delay of 54 days (range 5 to 345 days) after randomization. Medical group patients became eligible for coronary revascularization if they and their physicians so desired, typically because of the development of unacceptable angina despite medical therapy.

In the CASS, each patient's employment status at entry and at the end of the follow-up year was classified as follows: (1) employed--either full- or part-time, or (2) not employed--retired, quit, or other. Obviously, the coding of employment status in CASS differs from that in the NHTS. It is nonetheless possible to recode the NHTS data to be consistent with the CASS data.

In the CASS, data on employment status were collected at baseline (time of evaluation) and at 1, 3, and 5 years following enrollment in the study. Since the NHTS is not a longitudinal study, it was impossible to collect employment data in the same manner as in the CASS. Indeed, data were retrospectively collected for several time periods. These time periods were as follows: (1) historically, (2) during the year prior to transplant, (3) at the time of evaluation, and (4) currently. To render the data roughly comparable with those

in the CASS, we have divided all living heart transplant recipients into three cohorts--those who have had their transplant one year or more, those who have had their transplant three years or more, and those who have had their transplant five years or more. Unfortunately, this method of segregating patients according to time periods does not make the results entirely compatible with those of the CASS. Most importantly, in the CASS, the employment status of the same individual is being compared over time while in the NHTS, cohorts of individuals are being compared over time.

2. RESULTS

The results of our comparative analysis of employment status are shown in Table 24-11. As this table reveals, heart transplant recipients are much less likely to be working than either CASS medical or surgical patients for every time period considered. At baseline, or time of evaluation, the differences are most striking as only 8.1 percent of the heart transplant recipients were working compared with 68.7 percent of the medically and 75.6 percent of the surgically managed patients in the CASS. Among heart transplant recipients who have had their heart transplants one year or more, 34.2 percent were working. Perhaps the most optimistic finding for heart transplant recipients revealed in Table 24-11 is that for every time period subsequent to baseline a larger percentage of patients were working than at baseline. For the CASS patients, the opposite is true--a smaller percentage of patients is working each time period following baseline.

Table 24-11
Employment Status of Living Heart Transplant Recipients Compared With
Patients in the Coronary Artery Surgery Study
(Expressed As A Percent of Total)

	BASELINE[1]			1-YEAR			3-YEAR			5-YEAR		
	CASS PATIENTS[2]		NHTS PATIENTS	CASS PATIENTS[2]		NHTS PATIENTS	CASS PATIENTS[2]		NHTS PATIENTS	CASS PATIENTS[2]		NHTS PATIENTS
EMPLOYMENT STATUS	MEDICAL	SURGICAL	TRANSPLANT	MEDICAL	SURGICAL	TRANSPLANT	MEDICAL	SURGICAL	TRANSPLANT	MEDICAL	SURGICAL	TRANSPLANT
WORKING (FULL-TIME OR PART-TIME)	68.7	75.6	8.1	67.5	71.1	34.2	60.3	64.7	36.0	57.7	57.7	27.3
NOT WORKING (DISABLED, RETIRED, STUDENT, ETC.)	31.3	24.4	91.9	32.5	28.9	65.8	39.7	35.3	64.0	42.3	42.3	72.7

[1]For heart transplant recipients this period is set equal to time of evaluation.

[2]Excludes patients who died.

E. COMPARISONS WITH THE NATIONAL KIDNEY DIALYSIS AND KIDNEY TRANSPLANTATION STUDY

Data are available for comparing the employment status of heart transplant recipients with that of end-stage renal disease patients who have received kidney transplants or who are on kidney dialysis. These data were collected as part of the National Kidney Dialysis and Kidney Transplantation Study and are more fully described below.

1. DESCRIPTION OF THE NATIONAL KIDNEY DIALYSIS AND KIDNEY TRANSPLANTATION STUDY

Data for the National Kidney Dialysis and Kidney Transplantation Study were obtained by a survey of 859 patients from eleven dialysis and transplant centers in the U.S. (Evans et al., 1984). Two-stage sampling was used to select a purposive sample of dialysis and transplant centers and a probability sample of dialysis and transplant patients (Kish, 1965). First, a purposive sample of centers was selected to maximize variation with respect to geographical distribution, size and type of facility, academic affiliation, ownership, availability of a home dialysis training program, number of patients by treatment modality, and the urban/rural nature of the service area. Second, a random probability sample of patients stratified by treatment modality at the time of study (home hemodialysis, in-center hemodialysis, continuous ambulatory peritoneal dialysis (CAPD)/continuous cycling peritoneal dialysis (CCPD), and transplantation) was drawn from each facility.

All continuous peritoneal dialysis (CPD) patients at the eleven centers were included in the study, and samples of home

hemodialysis, in-center hemodialysis, and transplant patients with functioning grafts were randomly selected from the population of patients at each center. All patients were 18 years of age or older. Of 859 patients interviewed, 287 were on home hemodialysis, 347 were on in-center hemodialysis, 81 were CAPD/CCPD patients and 144 were transplanted (74 with a living related donor and 70 with a cadaver donor transplant).

It is noteworthy that direct inference of the study results to the general dialysis and transplant population is not possible given this sample design. A national probability sample survey would be required to make such inferences, but such a study is unlikely to be undertaken because of cost and logistical problems.

Data were collected from patients, medical records, and from a health care professional familiar with each patient's functional status. Information on sociodemographic and medical variables, employment status and subjective indicators of quality of life were obtained from the patient during a personal interview. With consent, medical information was abstracted from the medical record. In addition, a nephrologist, transplant surgeon, social worker, or nurse familiar with the patient's functional status recorded specific comorbid conditions and the extent to which physical activity was limited.

To insure that the data acquired were of high quality, persons responsible for collection of the study data underwent an intense three-day training session in Seattle prior to initiation of data collection activities. Uniform study procedures were followed at

each center. Each data collector was provided with an extensive procedures manual which included question-by-question specifications for all data items contained in each of the data collection instruments. Routine contact was made on a weekly basis with all data collectors.

The overall response rate for the two major patient-related data collection instruments was excellent. Completed patient interviews and medical records abstraction forms were obtained for 90 percent of the patients ultimately considered eligible for the study.

2. RESULTS

In comparing the results from the National Kidney Dialysis and Kidney Transplantation Study with those of the National Heart Transplantation Study, all patients have, once again, been divided into three cohorts. Those who have had their transplant or have been on kidney dialysis one-year or more, three-years or more, and five-years or more. For purposes of this analysis we have also defined a baseline period which is defined as the year prior to transplantation or first maintenance dialysis. Table 24-12 shows the baseline employment status for all patient groups. As shown here, heart transplant recipients were much less likely to be working during the baseline period than any of the dialysis patient groups or the kidney transplant recipients.

Among patients who have been treated one-year or more by dialysis or transplantation (see Table 24-13), 49.1 percent of the kidney transplant patients were working, 37.0 percent of the home hemodialysis patients, 34.2 percent of the heart transplant recipients,

Table 24-12
Cohort Analysis of the Baseline Work Status of Heart Transplant Recipients, Kidney Transplant Recipients, and Kidney Dialysis Patients

TIME PERIOD: BASELINE

	[1] HEART TRANSPLANT RECIPIENTS	[2] KIDNEY TRANSPLANT RECIPIENTS	[2] HOME HEMODIALYSIS PATIENTS	[2] IN-CENTER HEMODIALYSIS PATIENTS	[2] CONTINUOUS PERITONEAL DIALYSIS PATIENTS	[2] ALL DIALYSIS PATIENTS
EMPLOYED FULL-TIME	46.1	59.7	64.1	58.4	55.6	60.4
EMPLOYED PART-TIME	9.2	4.9	5.9	8.7	4.9	7.1
EMPLOYED BUT TEMPORARILY LAID OFF	0.0	0.0	0.0	.3	1.2	.3
UNEMPLOYED, LOOKING FOR WORK	0.0	0.0	0.0	.6	0.0	.3
UNEMPLOYED, NOT LOOKING FOR WORK	0.0	.7	.3	1.7	1.2	1.1
UNABLE TO WORK BECAUSE OF HEALTH (DISABLED)	33.6	2.8	8.4	8.7	14.8	9.2
HOMEMAKER	3.3	10.4	11.1	11.3	9.9	11.1
STUDENT (FULL-TIME)	5.3	20.8	7.3	2.9	2.5	4.6
RETIRED	2.6	.7	2.8	7.5	9.9	5.9
OTHER	0.0	0.0	0.0	0.0	0.0	0.0

[1]Baseline equals during the year prior to heart transplantation.

[2]Baseline equals during the year prior to first maintenance dialysis treatment or first transplant, whichever came first.

Table 24-13
Cohort Analysis of the Work Status of Heart Transplant Recipients,
Kidney Transplant Recipients, and Kidney Dialysis Patients
After One-Year Or More

	TIME PERIOD: ONE-YEAR OR MORE					
	HEART TRANSPLANT RECIPIENTS	KIDNEY TRANSPLANT RECIPIENTS	HOME HEMODIALYSIS PATIENTS	IN-CENTER HEMODIALYSIS PATIENTS	CONTINUOUS PERITONEAL DIALYSIS PATIENTS	ALL DIALYSIS PATIENTS
EMPLOYED FULL-TIME	28.8	43.1	28.2	12.6	8.3	18.9
EMPLOYED PART-TIME	5.4	6.0	8.8	6.9	0.0	7.2
EMPLOYED BUT TEMPORARILY LAID OFF	0.0	0.0	1.3	0.4	0.0	0.7
UNEMPLOYED, LOOKING FOR WORK	4.5	6.0	2.6	3.6	0.0	3.0
UNEMPLOYED, NOT LOOKING FOR WORK	0.0	2.6	0.4	3.2	8.3	2.4
UNABLE TO WORK BECAUSE OF HEALTH (DISABLED)	46.8	24.1	37.4	48.0	55.6	44.1
HOMEMAKER	3.6	13.8	10.1	9.4	19.4	10.4
STUDENT (FULL-TIME)	2.7	3.4	4.4	1.1	0.0	2.4
RETIRED	8.1	0.9	6.6	14.8	8.3	10.9
OTHER	0.0	0.0	0.0	0.0	0.0	0.0

and 19.5 percent of the in-center hemodialysis patients. At three or more years, (see Table 24-14) 51.8 percent of the kidney transplant patients were working followed by 38.1 percent of the home hemodialysis patients, 36.0 percent of the heart transplant recipients, and 28.9 percent of the in-center hemodialysis patients. Finally, at five-years (see Table 24-15), 49.2 percent of the kidney transplant recipients were working, followed by 42.7 percent of the home hemodialysis patients, 27.3 percent of the heart transplant recipients, and 14.9 percent of the in-center hemodialysis patients.

The foregoing results are summarized in Table 24-16, which clearly shows that kidney transplant recipients, except at baseline, are more likely to be working at all time periods than any other patient group. They are generally followed by home hemodialysis patients, then heart transplant recipients, and then in-center hemodialysis patients.

F. CONCLUSION

The results on the employment status of heart transplant recipients presented in this chapter are not as optimistic as those reported in the literature. When compared with their historical work status, 47.9 percent fewer patients are now employed (79.5 percent versus 31.6 percent). Even when compared with the year prior to their heart transplant, 23.7 percent fewer patients are employed (55.3 percent versus 31.6 percent). Yet, when compared with their employment status at time of evaluation, 23.5 percent more heart transplant recipients are currently working (8.1 percent versus 31.6 percent).

Table 24-14
Cohort Analysis of the Work Status of Heart Transplant Recipients,
Kidney Transplant Recipients, and Kidney Dialysis Patients
After Three Years Or More

	TIME PERIOD: THREE-YEARS OR MORE					
	HEART TRANSPLANT RECIPIENTS	KIDNEY TRANSPLANT RECIPIENTS	HOME HEMODIALYSIS PATIENTS	IN-CENTER HEMODIALYSIS PATIENTS	CONTINUOUS PERITONEAL DIALYSIS PATIENTS	ALL DIALYSIS PATIENTS
EMPLOYED FULL-TIME	32.0	44.4	28.4	11.1	0.0	19.1
EMPLOYED PART-TIME	4.0	7.4	9.7	7.8	0.0	8.7
EMPLOYED BUT TEMPORARILY LAID OFF	0.0	0.0	0.7	0.0	0.0	0.3
UNEMPLOYED, LOOKING FOR WORK	2.0	6.2	1.5	3.9	0.0	2.8
UNEMPLOYED, NOT LOOKING FOR WORK	0.0	3.7	0.0	3.3	0.0	1.7
UNABLE TO WORK BECAUSE OF HEALTH (DISABLED)	48.0	21.0	37.3	45.8	0.0	41.7
HOMEMAKER	2.0	11.1	11.9	10.5	100.0	11.5
STUDENT (FULL-TIME)	2.0	4.9	4.5	0.7	0.0	2.4
RETIRED	10.0	1.2	6.0	17.0	0.0	11.8
OTHER	0.0	0.0	0.0	0.0	0.0	0.0

Table 24-15
Cohort Analysis of the Work Status of Heart Transplant Recipients,
Kidney Transplant Recipients, and Kidney Dialysis Patients
After Five Years Or More

TIME PERIOD: FIVE-YEARS OR MORE

	HEART TRANSPLANT RECIPIENTS	KIDNEY TRANSPLANT RECIPIENTS	HOME HEMODIALYSIS PATIENTS	IN-CENTER HEMODIALYSIS PATIENTS	CONTINUOUS PERITONEAL DIALYSIS PATIENTS	ALL DIALYSIS PATIENTS
EMPLOYED FULL-TIME	27.3	42.6	30.5	10.8	0.0	21.2
EMPLOYED PART-TIME	0.0	6.6	12.2	4.1	0.0	8.3
EMPLOYED BUT TEMPORARILY LAID OFF	0.0	0.0	0.0	0.0	0.0	0.0
UNEMPLOYED, LOOKING FOR WORK	0.0	8.2	0.0	4.1	0.0	1.9
UNEMPLOYED, NOT LOOKING FOR WORK	0.0	4.9	0.0	2.7	0.0	1.3
UNABLE TO WORK BECAUSE OF HEALTH (DISABLED)	57.6	19.7	34.1	48.6	0.0	41.0
HOMEMAKER	3.0	11.5	13.4	13.5	0.0	13.5
STUDENT (FULL-TIME)	3.0	4.9	4.9	0.0	0.0	2.6
RETIRED	9.1	1.6	4.9	16.2	0.0	10.3
OTHER	0.0	0.0	0.0	0.0	0.0	0.0

Table 24-16
Work Status of Different Patient Groups At Different Time Periods

	PERCENT OF PATIENTS WORKING			
PATIENT GROUP	BASELINE[1]	1-YEAR	3-YEARS	5-YEARS
Heart Transplant Recipients	55.3	34.2	36.0	27.3
Kidney Transplant Recipients	64.6	49.1	51.8	49.2
Home Hemodialysis Patients	70.0	37.0	38.1	42.7
In-Center Hemodialysis Patients	67.1	19.5	18.9	14.9
Continuous Peritoneal Dialysis Patients	60.5	8.3	0.0	0.0
All Dialysis Patients	67.5	26.1	27.8	29.5

[1]Baseline equals during the year prior to transplantation.

Comparing heart transplant recipients with CASS medically and surgically managed patients does not yield a much brighter picture either, however. For every time period except baseline, a smaller percentage of heart transplant recipients are employed than either medically or surgically managed patients in the CASS study. Given the nature of their condition, perhaps it is unwarranted to expect that heart transplant recipients will achieve the same level of rehabilitation as patients with coronary artery disease who are medically and surgically managed. Perhaps their condition has been so life threatening that a return to work is too much to expect. Clearly, the results of some studies of patients who have received coronary artery bypass grafts have been no more optimistic than those presented here for heart transplant recipients.

The results presented in this chapter could be criticized because we have used cross-sectional data to look at cohorts of patients. In other words, it could be argued that we should look at the same patients at several points in time longitudinally. While this is not possible with these data, we have, however, limited our analyses to only those patients who were working during the year prior to their heart transplant. The posttransplant employment results are somewhat different from those presented in Table 24-11. For patients who had their heart transplant one year or more, 22.0 percent were working. Of those who had their heart transplant three years or more, 27.8 percent were working. Finally, of those who had their transplants five years or more, 31.3 percent were working. In Table 24-11, the comparable percentages were as follows: 34.2 percent at one year or

more, 36.0 percent at three years or more, and 27.3 percent at five years or more.

We have also analyzed the kidney transplant and kidney dialysis data in a similar fashion, that is, controlling for prior work status. The results are shown in Table 24-17. As shown here, for patients who have had their transplants or been on dialysis one year or more, kidney transplant recipients are the most likely to be working (48.6 percent), followed by home hemodialysis patients (42.6 percent), then in-center hemodialysis patients (26.0 percent), and then heart transplant recipients (22.0 percent). Among patients who have had their transplant or been on dialysis five years or more, kidney transplant recipients remain the most likely to be working (51.3 percent), followed by home hemodialysis patients (43.9 percent), and then heart transplant recipients (31.3 percent). At this time period, heart transplant recipients compare favorably with the all dialysis patient group. Additional detailed tables on current work status controlling for prior work status have been included as Appendix 24-B.

While this chapter has examined employment status in considerable detail, it is only one indicator of the quality of life of heart transplant recipients. There are many other indicators that will be examined in subsequent chapters of this report. In many respects, employment status is the most visible social worth criterion that can be applied in the study of medical interventions. Ultimately, however, it cannot be the sole criterion upon which judgements of quality of life and social worth are made.

Table 24-17
Work Status of Different Patient Groups At Different
Time Periods Controlling For Baseline Work Status

	PERCENT OF PATIENTS WORKING		
PATIENT GROUP	1-YEAR	3-YEARS	5-YEARS
Heart Transplant Recipients	22.0	27.8	31.3
Kidney Transplant Recipients	48.6	53.2	51.3
Home Hemodialysis Patients	42.6	42.1	43.9
In-Center Hemodialysis Patients	26.0	23.6	16.7
Continuous Peritoneal Dialysis Patients	13.6	0.0	0.0
All Dialysis Patients	32.4	32.4	30.6

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APPENDIX 24-A

OCCUPATIONAL CATEGORIES

APPENDIX A

Occupation Classification

(3-digit)

Census Code	PROFESSIONAL, TECHNICAL, AND KINDRED WORKERS
001	Accountants
002	Architects
	Computer specialists
003	Computer programmers
004	Computer systems analysts
005	Computer specialists, n.e.c.
	Engineers
006	Aeronautical and astronautical engineers
010	Chemical engineers
011	Civil engineers
012	Electrical and electronic engineers
013	Industrial engineers
014	Mechanical engineers
015	Metallurgical and materials engineers
020	Mining engineers
021	Petroleum engineers
022	Sales engineers
023	Engineers, n.e.c.
024	Farm management advisors
025	Foresters and conservationists
026	Home management advisors
	Lawyers and judges
030	Judges
031	Lawyers
	Librarians, archivists, and curators
032	Librarians
033	Archivists and curators
	Mathematical specialists
034	Actuaries
035	Mathematicians
036	Statisticians
	Life and physical scientists
042	Agricultural scientists
043	Atmospheric and space scientists
044	Biological scientists
045	Chemists
051	Geologists
052	Marine scientists
053	Physicists and astronomers
054	Life and physical scientists, n.e.c.
055	Operations and systems researchers and analysts
056	Personnel and labor relations workers
	Physicians, dentists, and related practitioners
061	Chiropractors
062	Dentists
063	Optometrists

064	Pharmacists
065	Physicians, medical and osteopathic
071	Podiatrists
072	Veterinarians
073	Health practitioners, n.e.c.
	Nurses, dietitians, and therapists
074	Dietitians
075	Registered nurses
076	Therapists
	Health technologists and technicians
080	Clinical laboratory technologists and technicians
081	Dental hygienists
082	Health record technologists and technicians
083	Radiologic technologists and technicians
084	Therapy assistants
085	Health technologists and technicians, n.e.c.
	Religious workers
086	Clergymen
090	Religious workers, n.e.c.
	Social scientists
091	Economists
092	Political scientists
093	Psychologists
094	Sociologists
095	Urban and regional planners
096	Social scientists, n.e.c.
	Social and recreation workers
100	Social workers
101	Recreation workers
	Teachers, college and university
102	Agriculture teachers
103	Atmospheric, earth, marine, and space teachers
104	Biology teachers
105	Chemistry teachers
110	Physics teachers
111	Engineering teachers
112	Mathematics teachers
113	Health specialties teachers
114	Psychology teachers
115	Business and commerce teachers
116	Economic teachers
120	History teachers
121	Sociology teachers
122	Social science teachers, n.e.c.
123	Art, drama, and music teachers
124	Coaches and physical education teachers
125	Education teachers
126	English teachers
130	Foreign language teachers
131	Home economics teachers
132	Law teachers
133	Theology teachers
134	Trade, industrial, and technical teachers

135 Miscellaneous teachers, college and university
140 Teachers, college and university, subject not specified
Teachers, except college and university
141 Adult education teachers
142 Elementary school teachers
143 Prekindergarten and kindergarten teachers
144 Secondary school teachers
145 Teachers, except college and university, n.e.c.
Engineering and science technicians
150 Agriculture and biological technicians, except health
151 Chemical technicians
152 Draftsmen
153 Electrical and electronic engineering technicians
154 Industrial engineering technicians
155 Mechanical engineering technicians
156 Mathematical technicians
161 Surveyors
162 Engineering and science technicians, n.e.c.
Technicians, except health, and engineering and science
163 Airplane pilots
164 Air traffic controllers
165 Embalmers
170 Flight engineers
171 Radio operators
172 Tool programmers, numerical control
173 Technicians, n.e.c.
174 Vocational and educational counselors
Writers, artists, and entertainers
175 Actors
180 Athletes and kindred workers
181 Authors
182 Dancers
183 Designers
184 Editors and reporters
185 Musicians and composers
190 Painters and sculptors
191 Photographers
192 Public relations men and publicity wRiters
193 Radio and television announcers
194 Writers, artists, and entertainers, n.e.c.
195 Research workers, not specified

MANAGERS AND ADMINISTRATORS, EXCEPT FARM

201 Assessors, controllers, and treasurers; local public administration
202 Bank officers and financial managers
203 Buyers and shippers, farm products

205	Buyers, wholesale and retail trade
210	Credit men
211	Funeral directors
212	Health administrators
213	Construction inspectors, public administration
215	Inspectors, except construction, public administrati
216	Managers and superintendents, building
220	Office managers, n.e.c.
221	Officers, pilots, and pursers; ship
222	Officials and administrators; public administration, n.e.c.
223	Officials of lodges, societies, and unions
224	Postmasters and mail superintendents
225	Purchasing agents and buyers, n.e.c.
226	Railroad conductors
230	Restaurant, cafeteria, and bar managers
231	Sales managers and department heads, retail trade
233	Sales managers, except retail trade
235	School administrators, college
240	School administrators, elementary and secondary
245	Managers and administrators, n.e.c.

SALES WORKERS

260	Advertising agents and salesmen
261	Auctioneers
262	Demonstrators
264	Hucksters and peddlers
265	Insurance agents, brokers, and underwriters
266	Newsboys
270	Real estate agents and brokers
271	Stock and bond salesmen
280	Salesmen and sales clerks, n.e.c.
281	Sales representatives, manufacturing industries
282	Sales representatives, wholesale trade
283	Sales clerks, retail trade
284	Salesmen, retail trade
285	Salesmen of services and construction
296	Sales workers - allocated

CLERICAL AND KINDRED WORKERS

301	Bank tellers
303	Billing clerks
305	Bookkeepers
310	Cashiers
311	Clerical assistants, social welfare
312	Clerical supervisors, n.e.c.
313	Collectors, bill and account
314	Counter clerks, except food
315	Dispatchers and starters, vehicle
320	Enumerators and interviewers

321 Estimators and investigators, n.e.c.
323 Expediters and production controllers
325 File clerks
326 Insurance adjusters, examiners, and investigators
330 Library attendants and assistants
331 Mail carriers, post office
332 Mail handlers, except post office
333 Messengers and office boys
334 Meter readers, utilities
Office machine operators
341 Bookkeeping and billing machine operators
342 Calculating machine operators
343 Computer and peripheral equipment operators
344 Duplicating machine operators
345 Key punch operators
350 Tabulating machine operators
355 Office machine operators, n.e.c.
360 Payroll and timekeeping clerks
361 Postal clerks
362 Proofreaders
363 Real estate appraisers
364 Receptionists
Secretaries
370 Secretaries, legal
371 Secretaries, medical
372 Secretaries, n.e.c.
374 Shipping and receiving clerks
375 Statistical clerks
376 Stenographers
381 Stock clerks and storekeepers
382 Teacher aides, exc. school monitors
383 Telegraph messengers
384 Telegraph operators
385 Telephone operators
390 Ticket, station, and express agents
391 Typists
392 Weighers
394 Miscellaneous clerical workers
395 Not specified clerical workers

CRAFTSMEN AND KINDRED WORKERS

401 Automobile accessories installers
402 Bakers
403 Blacksmiths
404 Boilermakers
405 Bookbinders
410 Brickmasons and stonemasons
411 Brickmasons and stonemasons, apprentices
412 Bulldozer operators
413 Cabinetmakers
415 Carpenters

416 Carpenter apprentices
420 Carpet installers
421 Cement and concrete finishers
422 Compositors and typesetters
423 Printing trades apprentices, exc. pressmen
424 Cranemen, derrickmen, and hoistmen
425 Decorators and window dressers
426 Dental laboratory technicians
430 Electricians
431 Electrician apprentices
433 Electric power linemen and cablemen
434 Electrotypers and stereotypers
435 Engravers, exc. photoengravers
436 Excavating, grading, and road machine operators; exc. bulldozer
440 Floor layers, exc. tile setters
441 Foremen, n.e.c.
442 Forgemen and hammermen
443 Furniture and wood finishers
444 Furriers
445 Glaziers
446 Heat treaters, annealers, and temperers
450 Inspectors, scalers, and graders; log and lumber
452 Inspectors, n.e.c.
453 Jewelers and watchmakers
454 Job and die setters, metal
455 Locomotive engineers
456 Locomotive firemen
461 Machinists
462 Machinists apprentices
Mechanics and repairmen
470 Air conditioning, heating, and refrigeration
471 Aircraft
472 Automobile body repairmen
473 Automobile mechanics
474 Automobile mechanic apprentices
475 Data processing machine repairmen
480 Farm implement
481 Heavy equipment mechanics, incl. diesel
482 Household appliance and accessory installers and mechanics
483 Loom fixers
484 Office machine
485 Radio and television
486 Railroad and car shop
491 Mechanic, exc. auto, apprentices
492 Miscellaneous mechanics and repairmen
495 Not specified mechanics and repairmen
501 Millers; grain, flour, and feed
502 Millwrights
503 Molders, metal
504 Molder apprentices
505 Motion picture projectionists

506 Opticians and lens grinders and polishers
510 Painters, construction and maintenance
511 Painter apprentices
512 Paperhangers
514 Pattern and model makers, exc. paper
515 Photoengravers and lithographers
516 Piano and organ tuners and repairmen
520 Plasters
521 Plasterer apprentices
522 Plumbers and pipe fitters
523 Plumber and pipe fitter apprentices
525 Power station operators
530 Pressmen and plate printers, printing
531 Pressman apprentices
533 Rollers and finishers, metal
534 Roofers and slaters
535 Sheetmetal workers and tinsmiths
536 Sheetmetal apprentices
540 Shipfitters
542 Shoe repairmen
543 Sign painters and letterers
545 Stationary engineers
546 Stone cutters and stone carvers
550 Structural metal craftsmen
551 Tailors
552 Telephone installers and repairmen
554 Telephone linemen and splicers
560 Tile setters
561 Tool and die makers
562 Tool and die maker apprentices
563 Upholsterers
571 Specified craft apprentices, n.e.c.
572 Not specified apprentices
575 Craftsmen and kindred workers, n.e.c.
580 Former members of the Armed Forces

OPERATIVE, EXCEPT TRANSPORT

601 Asbestos and insulation workers
602 Assemblers
603 Blasters and powdermen
604 Bottling and canning operatives
605 Chainmen, rodmen, and axmen, surveying
610 Checkers, examiners, and inspectors, manufacturing
611 Clothing ironers and pressers
612 Cutting operatives, n.e.c.
613 Dressmakers and seamstresses, except factory
614 Drillers, earth
615 Dry wall installers and lathers
620 Dyers
621 Filers, polishers, sanders, and buffers
622 Furnacemen, smeltermen, and pourers

623 Garage workers and gas station attendants
624 Graders and sorters, manufacturing
625 Produce graders and packers, exc. factory and farm
626 Heaters, metal
630 Laundry and dry cleaning operatives, n.e.c.
631 Meat cutters and butchers, exc. manufacturing
633 Meat cutters and butchers, manufacturing
634 Meat wrappers, retail trade
635 Metal platers
636 Milliners
640 Mine operatives, n.e.c.
641 Mixing operative
642 Oilers and greasers, exc. auto
643 Packers and wrappers, exc. meat and produce
644 Painters, manufactured articles
645 Photographic process workers
Precision machine operatives
650 Drill press operatives
651 Grinding machine operatives
652 Lathe and milling machine operatives
653 Precision machine operatives, n.e.c.
656 Punch and stamping press operatives
660 Riveters and fasteners
661 Sailors and deckhands
662 Sawyers
663 Sewers and stitchers
664 Shoemaking machine operatives
665 Solderers
666 Stationary firemen
Textile operatives
670 Carding, lapping, and combing operatives
671 Knitters, loopers, and toppers
672 Spinners, twisters, and winders
673 Weavers
674 Textile operatives, n.e.c.
680 Welders and flame-cutters
681 Winding operatives, n.e.c.
690 Machine operatives, miscellaneous specified
692 Machine operatives, not specified
694 Miscellaneous operatives
695 Not specified operatives

TRANSPORT EQUIPMENT OPERATIVES

701 Boatmen and canalmen
703 Busdrivers
704 Conductors and motormen, urban rail transit
705 Deliverymen and routemen
706 Fork lift and tow motor operatives
710 Motormen; mine, factory, logging camp, etc.
711 Parking attendants
712 Railroad brakemen

713 Railroad switchmen
714 Taxicab drivers and chauffeurs
715 Truck drivers

LABORERS, EXCEPT FARM

740 Animal caretakers, exc. farm
750 Carpenters' helpers
751 Construction laborers, exc. carpenters' helpers
752 Fishermen and oystermen
753 Freight and material handlers
754 Garbage collectors
755 Gardeners and groundskeepers, exc. farm
760 Longshoremen and stevedores
761 Lumbermen, raftsmen, and woodchoppers
762 Stockhandlers
763 Teamsters
764 Vehicle washers and equipment cleaners
770 Warehousemen, n.e.c.
780 Miscellaneous laborers
785 Not specified laborers

FARMERS AND FARM MANAGERS

801 Farmers (owners and tenants)
802 Farm managers

FARM LABORERS AND FARM FOREMEN

821 Farm foremen
822 Farm laborers, wage workers
823 Farm laborers, unpaid family workers
824 Farm service laborers, self-employed

SERVICE WORKERS, EXC. PRIVATE HOUSEHOLD

Cleaning service workers
901 Chambermaids and maids, exc. private households
902 Cleaners and charwomen
903 Janitors and sextons
Food service workers
910 Bartenders
911 Busboys
912 Cooks, exc. private household
913 Dishwashers
914 Food counter and fountain workers
915 Waiters
916 Food service workers, n.e.c., exc. private household

921 Dental assistants
922 Health aides, exc. nursing
923 Health trainees
924 Lay midwives
925 Nursing aides, orderlies, and attendants
926 Practical nurses

Personal service workers

931 Airline stewardesses
932 Attendants, recreation and amusement
933 Attendants, personal service, n.e.c.
934 Baggage porters and bellhops
935 Barbers
940 Boarding and lodginghouse keepers
941 Bootblacks
942 Child care workers, exc. private household
943 Elevator operators
944 Hairdressers and cosmetologists
945 Personal service apprentices
950 Housekeepers, exc. private household
952 School monitors
953 Ushers, recreation and amusement
954 Welfare service aides

Protective service workers

960 Crossing guards and bridge tenders
961 Firemen, fire protection
962 Guards and watchmen
963 Marshals and constables
964 Policemen and detectives
965 Sheriffs and bailiffs

PRIVATE HOUSEHOLD WORKERS

980 Child care workers, private household
981 Cooks, private household
982 Housekeepers, private household
983 Laundresses, private household
984 Maids and servants, private household

APPENDIX 24-B

ADDITIONAL DETAILED TABLES ON CURRENT WORK STATUS CONTROLLING FOR PRIOR WORK STATUS

Table 24-B-1
Work Status of Different Patient Groups At One-Year Or More
Controlling For Prior Work Status

	TIME PERIOD: ONE-YEAR OR MORE					
	HEART TRANSPLANT RECIPIENTS	KIDNEY TRANSPLANT RECIPIENTS	HOME HEMODIALYSIS PATIENTS	IN-CENTER HEMODIALYSIS PATIENTS	CONTINUOUS PERITONEAL DIALYSIS PATIENTS	ALL DIALYSIS PATIENTS
EMPLOYED FULL-TIME	20.0	44.4	32.1	17.5	13.6	23.6
EMPLOYED PART-TIME	2.0	4.2	10.5	8.5	0.0	8.8
EMPLOYED BUT TEMPORARILY LAID OFF	0.0	0.0	1.9	0.5	0.0	1.1
UNEMPLOYED, LOOKING FOR WORK	6.0	9.7	2.5	3.7	0.0	2.9
UNEMPLOYED, NOT LOOKING FOR WORK	0.0	2.8	0.0	3.7	9.1	2.4
UNABLE TO WORK BECAUSE OF HEALTH (DISABLED)	54.0	33.3	41.4	53.4	63.6	48.8
HOMEMAKER	8.0	4.2	3.1	0.0	4.5	1.6
STUDENT (FULL-TIME)	2.0	1.4	2.5	0.5	0.0	1.3
RETIRED	8.0	0.0	6.2	12.2	9.1	9.4
OTHER	0.0	0.0	0.0	0.0	0.0	0.0
NUMBER OF CASES	50	72	162	189	22	373

Table 24-B-2
Work Status of Different Patient Groups At Three-Years Or More
Controlling For Prior Work Status

	TIME PERIOD: THREE YEARS OR MORE					
	HEART TRANSPLANT RECIPIENTS	KIDNEY TRANSPLANT RECIPIENTS	HOME HEMODIALYSIS PATIENTS	IN-CENTER HEMODIALYSIS PATIENTS	CONTINUOUS PERITONEAL DIALYSIS PATIENTS	ALL DIALYSIS PATIENTS
EMPLOYED FULL-TIME	27.8	48.9	31.6	15.1	0.0	22.9
EMPLOYED PART-TIME	0.0	4.3	10.5	8.5	0.0	9.5
EMPLOYED BUT TEMPORARILY LAID OFF	0.0	0.0	1.1	0.0	0.0	0.5
UNEMPLOYED, LOOKING FOR WORK	0.0	10.6	1.1	2.8	0.0	2.0
UNEMPLOYED, NOT LOOKING FOR WORK	0.0	4.3	0.0	3.8	0.0	2.0
UNABLE TO WORK BECAUSE OF HEALTH (DISABLED)	61.1	27.7	43.2	52.8	0.0	48.3
HOMEMAKER	5.6	2.1	4.2	0.0	0.0	2.0
STUDENT (FULL-TIME)	0.0	2.1	3.2	0.0	0.0	1.5
RETIRED	5.6	0.0	5.3	17.0	0.0	11.4
OTHER	0.0	0.0	0.0	0.0	0.0	0.0
NUMBER OF CASES	18	47	95	106	0	201

Table 24-B-3
Work Status of Different Patient Groups At Five-Years Or More
Controlling For Prior Work Status

TIME PERIOD: FIVE YEARS OR MORE

	HEART TRANSPLANT RECIPIENTS	KIDNEY TRANSPLANT RECIPIENTS	HOME HEMODIALYSIS PATIENTS	IN-CENTER HEMODIALYSIS PATIENTS	CONTINUOUS PERITONEAL DIALYSIS PATIENTS	ALL DIALYSIS PATIENTS
EMPLOYED FULL-TIME	31.3	48.6	31.6	13.0	0.0	22.5
EMPLOYED PART-TIME	0.0	2.7	12.3	3.7	0.0	8.1
EMPLOYED BUT TEMPORARILY LAID OFF	0.0	0.0	0.0	0.0	0.0	0.0
UNEMPLOYED, LOOKING FOR WORK	0.0	13.5	0.0	3.7	0.0	1.8
UNEMPLOYED, NOT LOOKING FOR WORK	0.0	5.4	0.0	3.7	0.0	1.8
UNABLE TO WORK BECAUSE OF HEALTH (DISABLED)	56.3	27.0	43.9	59.3	0.0	51.4
HOMEMAKER	6.3	2.7	5.3	0.0	0.0	2.7
STUDENT (FULL-TIME)	0.0	0.0	1.8	0.0	0.0	0.9
RETIRED	6.3	0.0	5.3	16.7	0.0	10.8
OTHER	0.0	0.0	0.0	0.0	0.0	0.0
NUMBER OF CASES	16	37	57	54	0	111

CHAPTER 25

AN ANALYSIS OF THE OBJECTIVE AND SUBJECTIVE QUALITY OF LIFE OF LIVING HEART TRANSPLANT RECIPIENTS

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A. INTRODUCTION

As described in Chapter 23, quality of life can be conceptualized as having two dimensions--one objective and the other subjective. We have previously demonstrated the utility of distinguishing between objective and subjective indicators of quality of life through quantitative analyses (Evans et al., 1984). We were able to show that, although correlated, independent measures of the objective and subjective aspects of quality of life are more highly correlated among themselves than they are with each other. In general, we have shown that chronically ill people are remarkably resilient. While their objective circumstances may seem intolerable to healthy individuals, the chronically ill frequently express a relatively high level of subjective quality of life. For example, a chronically ill person with marked disability (an objective indicator of quality of life) may express a high level of life satisfaction (a subjective indicator of quality of life). Therefore, to focus on merely objective indicators of quality of life may result in a distorted image of the quality of life of the chronically ill person as they judge it subjectively.

The primary goal of this chapter is to analyze both the objective and subjective quality of life of heart transplant recipients. In doing so, we will specifically examine three objective and three subjective quality of life indicators. The objective indicators are as follows: ability to work, functional impairment, and health status. The subjective indicators are psychological affect, well-being, and life satisfaction. As described in Chapter 23, all these indicators have been used in previous studies. The objective

indicators of quality of life reflect physical status while the subjective indicators reflect socioemotional status. Only one measure, that being health status (the Sickness Impact Profile), combines both a physical and psychosocial dimension into a total health status score.

B. VARIABLES

In Chapter 23 we have described at some length the various measures of quality of life used in the National Heart Transplantation Study. We will, once again, highlight that discussion to enable interpretation of the findings that are presented here. For more complete discussion of each of the measures, and for a copy of the exact questions asked to ascertain quality of life, the reader is referred to Chapter 23.

1. OBJECTIVE QUALITY OF LIFE INDICATORS

The Karnofsky Index was used as an overall indicator of functional impairment and is a measure of physical functional status ranging from 1 (normal; no complaints; no evidence of disease) to 10 (moribund; fatal processes progressing rapidly). The Karnofsky Index is displayed in Table 25-1.

A patient's ability to work was ascertained by asking the following simple question: "Are you now able to work for pay full-time, part-time, or not at all?" While it could be argued that ability to work is more subjective than objective, a correlation analysis does not support this.

Health status was ascertained using the Sickness Impact Profile (SIP). The SIP is a standardized questionnaire that measures

Table 25-1
Karnofsky Performance Status Index

Condition		Performance Status %	Comments
A.	Able to carry on normal activity and to work. No special care is needed.	100	Normal. No complaints. No evidence of disease.
		90	Able to carry on normal activity. Minor signs or symptoms of disease.
		80	Normal activity with effort. Some signs or symptoms of disease.
B.	Unable to work. Able to live at home, care for most personal needs. A varying degree of assistance is needed.	70	Cares for self. Unable to carry on normal activity or to do active work.
		60	Requires occasional assistance, but is able to care for most of his needs.
		50	Requires considerable assistance and frequent medical care.
C.	Unable to care for self. Requires equivalent of institutional or hospital care. Disease may be progressing rapidly.	40	Disabled. Requires special care and assistance. Severely disabled. Hospitalization is indicated although death is not imminent.
		20	Hospitalization necessary, very sick, active supportive treatment necessary.
		10	Moribund. Fatal processes progressing rapidly.
		0	Dead.

(See Karnofsky and Burchenal, 1949; Hutchinson et al., 1979; Gutman et al., 1981.)

sickness-related dysfunction. The SIP consists of 136 questions which are grouped in 12 categories (see Table 25-2), each describing an area of activity in which dysfunctional behavior may occur. A score for each of the categories may be calculated, as well as a psychosocial dimension score, a physical dimension score, and an overall SIP score. Total SIP scores range from 0 to 100 where a low score indicates good health status and a high score indicates poor health. As the level of dysfunction experienced by the subject rises, so does the SIP score (Bergner et al., 1981; 1984; Pollard et al., 1976; Bergner et al., 1976).

2. SUBJECTIVE QUALITY OF LIFE INDICATORS

The subjective indicators of quality of life include the Index of Psychological Affect, the Index of Overall Life Satisfaction, and the Index of Well-Being (Campbell et al., 1976; Campbell and Converse, 1980). The Index of Psychological Affect, based on eight bipolar items, describes how patients feel about their present life, and responses are averaged for a mean score. The Index of Overall Life Satisfaction is also based on bipolar responses. The Index of Well-Being is calculated by combining the Index of Overall Life Satisfaction and the Index of Psychological Affect (giving slightly more weight to the former).

Both the Index of Psychological Affect and the Index of Overall Life Satisfaction range from a low of 1.0 (completely dissatisfied) to a high of 7.0 (completely satisfied). The Index of Well-Being ranges between 2.1 and 14.7, where a score of 2.1 indicates low well-being and a score of 14.7 indicates high well-being.

Table 25-2
Categories and Sample Items From the Sickness Impact Profile

Category	Items Describing Behavior Related to	Selected Items
SR	Sleep and Rest	I sit during much of the day. I sleep or nap during the day.
E	Eating	I am eating no food at all, nutrition is taken through tubes or intraveneous fluids. I am eating special or different food.
W	Work	I am not working at all. I often act irritable toward my work associates.
HM	Home Management	I am not doing any of the maintenance or repair work around the house that I usually do. I am not doing heavy work around the house.
RP	Recreation and Pastimes	I am going out for entertainment less. I am not doing any of my usual physical recreation or activities.
A	Ambulation	I walk shorter distances or stop to rest often. I do not walk at all.
M	Mobility	I stay within one room. I stay away from home only for brief periods of time.
BCM	Body Care and Movement	I do not bathe myself at all, but am bathed by someone else. I am very clumsy in body movements.
SI	Social Interaction	I am doing fewer social activities with groups of people. I isolate myself as much as I can from the rest of the family.

Table 25-2 (Continued)
Categories and Sample Items From the Sickness Impact Profile

Category	Items Describing Behavior Related to	Selected Items
AB	Alertness Behavior	I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things. I sometimes behave as if I were confused or disoriented in place or time, for example, where I am, who is around, directions, what day it is.
EB	Emotional Behavior	I laugh or cry suddenly. I act irritable and impatient with myself, for example, talk badly about myself, swear at myself, blame myself for things that happen.
C	Communication	I am having trouble writing or typing. I do not speak clearly when I am under stress.

(See Gilson et al., 1979.)

C. STATISTICAL METHODS

All statistics presented in this chapter are descriptive. Statistical averages (means) and standard deviations are presented for heart transplant recipients only. In Chapter 26 a comparative analysis of quality of life will be presented wherein the quality of life of heart transplant recipients is compared with that of patients who are on kidney dialysis or have received a kidney transplant.

D. RESULTS

1. SOCIODEMOGRAPHIC CHARACTERISTICS

Table 25-3 summarizes the sociodemographic characteristics of the living heart transplant recipients included in these analyses. Sociodemographic factors may be critical to patient outcomes such as quality of life, however, results are not presented here which examine how quality of life differs among patients of various sociodemographic backgrounds.

2. CORRELATIONS AMONG OBJECTIVE AND SUBJECTIVE QUALITY OF LIFE INDICATORS

A separate correlation analysis was undertaken of the intercorrelations among the various objective and subjective indicators of quality of life. These results are presented in Table 25-4. As shown, with the exception of health status, intercorrelations between the subjective and objective indicators are much lower than either the objective measures separately or the subjective measures separately. This anomaly likely owes to the fact that the Sickness Impact Profile has both an objective and subjective dimension.

Table 25-3
Sociodemographic Chacteristics of Living Heart Transplant Recipients

AGE ($\bar{X}$)	42.4
SEX	
MALE (%)	87.5
FEMALE (%)	12.5
RACE	
BLACK (%)	3.3
WHITE (%)	87.5
OTHER (%)	9.2

Table 25-4
Correlation Analysis of Objective and Subjective
Quality of Life Indicators*

	OBJECTIVE INDICATORS			SUBJECTIVE INDICATORS		
	FUNCTIONAL IMPAIRMENT	ABILITY TO WORK	HEALTH STATUS	WELL-BEING	PSYCHOLOGICAL AFFECT	LIFE SATISFACTION
FUNCTIONAL IMPAIRMENT	1.00					
ABILITY TO WORK	-.11					
HEALTH STATUS	.34	-.38				
WELL-BEING	-.15	.06	-.60			
PSYCHOLOGICAL AFFECT	-.15	.07	-.61	.92		
LIFE SATISFACTION	-.13	.05	-.50	.93	.73	1.00

*See text for scoring of indicators.

Despite this, we feel it is reasonable to conclude, once again, that quality of life has both an objective and a subjective dimension.

3. DESCRIPTIVE FREQUENCY DISTRIBUTIONS FOR ALL QUALITY OF LIFE INDICATORS

Tables 25-5 through 25-9 present the frequency distribution for each quality of life indicator. As shown in Table 25-5, 66.3 percent of the living heart transplant recipients were reported by transplant center staff to be normal with no complaints or evidence of disease.

Although not shown in a separate table, 34 percent of the patients said they were able to work full-time, 24.7 percent said part-time, and 41.3 percent indicated that they were unable to work at all. Two patients did not respond to the question concerning ability to work.

Table 25-6 provides a summary of the distribution of the overall Sickness Impact Profile scores according to different ranges. SIP scores can range from 0 to 100. In preparing Table 25-6, overall SIP scores were calculated for all patients and then only for patients who had their heart transplant one year or more. The idea here is that patients who have had their heart transplants for less than one year have not yet made a complete recovery from their transplant experience. Therefore, the patients who have had their transplants for a year or more may more accurately reflect the health status implications of heart transplantation. As shown in Table 25-6, however, there are only minor differences between the distribution of the two patient groups. Since another comparison group of subjects has not been incorporated in these analyses, it is difficult to state

Table 25-5
Frequency Distribution for the Karnofsky Index

KARNOFSKY INDEX CATEGORY	PERCENT OF PATIENTS
NORMAL: NO COMPLAINTS: NO EVIDENCE OF DISEASE	66.3
ABLE TO CARRY ON NORMAL ACTIVITY: MINOR SIGNS AND SYMPTOMS OF DISEASE	23.2
NORMAL ACTIVITY WITH EFFORT: SOME SIGNS AND SYMPTOMS OF DISEASE	6.1
CARE FOR SELF: UNABLE TO CARRY ON NORMAL ACTIVITY OR DO ACTIVE WORK	0.6
REQUIRES OCCASIONAL ASSISTANCE BUT IS ABLE TO CARE FOR MOST OF OWN NEEDS	2.8
REQUIRES CONSIDERABLE ASSISTANCE AND FREQUENT MEDICAL CARE	1.1
DISABLED: REQUIRES SPECIAL CARE AND ASSISTANCE	0.0
SEVERELY DISABLED: HOSPITALIZATION IS INDICATED ALTHOUGH DEATH NOT IMMINENT	0.0
VERY SICK: HOSPITALIZATION NECESSARY	0.0
MORIBUND: FATAL PROCESSES PROGRESSING RAPIDLY	0.0

Table 25-6
Frequency Distribution for the Sickness Impact Profile

OVERALL SIP SCORE	PERCENT OF ALL LIVING PATIENTS	PERCENT OF LIVING PATIENTS WITH TRANSPLANT ONE YEAR OR MORE
0 - 4	34.9	38.5
5 - 9	30.2	27.5
10 - 14	12.1	11.0
15 - 19	11.4	10.1
20 - 24	6.7	7.3
25 - 29	2.0	1.8
30 - 34	1.3	1.8
35 - 39	0.7	0.9
40 - 44	0.0	0.0
45 - 49	0.7	0.9
50 - 100	0.0	0.0

Table 25-7
Frequency Distribution for the Index of Well-Being

INDEX OF WELL-BEING SCORE	PERCENT
2.10 - 7.04	7.9
7.05 - 9.04	15.1
9.05 - 10.04	5.9
10.05 - 10.54	5.9
10.55 - 11.04	9.9
11.05 - 11.54	9.9
11.55 - 12.04	3.3
12.05 - 12.54	7.9
12.55 - 13.04	9.2
13.05 - 13.54	6.6
13.55 - 14.04	6.6
14.05 - 14.54	2.0
14.55 - 14.70	9.9

DESCRIPTIVE STATISTICS	
MEAN	11.113
STANDARD DEVIATION	2.534
RANGE (POSSIBLE SCORES)	2.1-14.7
N	152

Table 25-8
Frequency Distribution for the Index of Psychological Affect

INDEX OF PSYCHOLOGICAL AFFECT SCORE	PERCENT
1.00 - 1.94	0.7
1.95 - 2.94	4.6
2.95 - 3.94	9.9
3.95 - 4.44	8.6
4.45 - 4.94	7.9
4.95 - 5.24	4.6
5.25 - 5.44	3.9
5.45 - 5.74	9.2
5.75 - 5.94	3.3
5.95 - 6.24	7.2
6.25 - 6.44	11.2
6.45 - 6.74	7.2
6.75 - 7.00	21.7

DESCRIPTIVE STATISTICS	
MEAN	5.490
STANDARD DEVIATION	1.319
RANGE (POSSIBLE SCORES)	1.0-7.0
N	152

Table 25-9
Frequency Distribution for the Index of Overall Life Satisfaction

OVERALL LIFE SATISFACTION	PERCENT
COMPLETELY DISSATISFIED	0.7
VERY DISSATISFIED	1.3
DISSATISFIED	11.8
NEUTRAL	12.5
SATISFIED	33.6
VERY SATISFIED	26.3
COMPLETELY SATISFIED	13.8
DESCRIPTIVE STATISTICS	
MEAN	5.112
STANDARD DEVIATION	1.279
RANGE (POSSIBLE SCORES)	1.0-7.0
N	152

the precise meaning of these SIP scores. In Chapter 26, comparisons will be made with several other patient groups.

Tables 25-7 through 25-9 summarize the distribution of responses to each of the subjective quality of life indicators. Most apparent here are the relatively high scores reported by the heart transplant recipients. All scores are unadjusted for age, sex, and race although it is noteworthy that such adjustments do not produce remarkably different quality of life scores. Given this, we felt it was unnecessary to report adjusted scores.

On a scale of 2.1 to 14.7, patients reported a mean well-being score of 11.113 which represents a relatively high score on this index. However, as shown in Table 25-7, patients were fairly equally distributed across various ranges of scores.

With regard to psychological affect, that is, how positive they feel about themselves, on a range of 1.0 to 7.0, the heart transplant recipients had a mean score of 5.490. As shown in Table 25-8, the scores on this index were slightly more skewed than those on the Index of Well-Being, as nearly 22.0 percent of the patients reported a very high score on psychological affect.

Finally, on the Index of Overall Life Satisfaction with a range of 1.0 to 7.0, heart transplant recipients had a mean score of 5.112. Here again, scores were more skewed in the positive rather than negative direction as nearly 74.0 percent of the patients had a positive assessment of their overall life satisfaction.

4. SUMMARY SCORES ON ALL QUALITY OF LIFE INDICATORS

To summarize the results of our analysis of quality of life, a mean or average score and a standard deviation has been computed for each indicator. These scores are shown in Table 25-10. In the absence of comparison groups, these scores are difficult to interpret. On the Karnofsky Index of physical functioning, heart transplant recipients had a very low overall score indicating that they are relatively free of impairment. This assessment of physical functioning, it should be noted, was made by a person at each transplant center who has been actively involved in the care of the patient or was familiar with the patient's level of functioning. This perhaps accounts in part for the difference between the scores on the Karnofsky Index and those on the Sickness Impact Profile. The SIP health status scores indicate that heart transplant recipients are impaired. The SIP is a standard questionnaire which is completed by the patient. Thus, there appears to be a marked discrepancy between how patients judge their functional ability and how the medical professionals responsible for their care do. Finally, the average score of patients on our ability to work measure was 57.88. Again, the patients have a lower score on this index than would seem reasonable given their Karnofsky scores.

With regard to subjective quality of life, the heart transplant recipients fair much better. On all measures--well-being, psychological affect, and life satisfaction--the patients scored very high indicating that they have a high quality of life. This, undoubtedly, is surprising to most clinicians since it is generally felt that the quality of life of individuals who have compromised

Table 25-10
Summary Quality of Life Scores for Living
Heart Transplant Recipients

QUALITY OF LIFE INDICATORS	MEAN SCORE	STANDARD DEVIATION	RANGE OF POSSIBLE VALUES
OBJECTIVE QUALITY OF LIFE			
FUNCTIONAL IMPAIRMENT	1.47	.77	1.0 - 10.0
ABILITY TO WORK	57.88	49.55	0.0 - 100.0
HEALTH STATUS	9.60	9.01	0.0 - 100.0
SUBJECTIVE QUALITY OF LIFE			
WELL-BEING	11.11	2.53	2.1 - 14.7
PSYCHOLOGICAL AFFECT	5.49	1.32	1.0 - 7.0
LIFE SATISFACTION	5.11	1.28	1.0 - 7.0

health status (e.g., a chronic or terminal disorder) is necessarily much lower than that of a person with uncompromised health. Quite surprisingly, this assumption, although having validity for objective quality of life indicators, does not square with the subjective assessments heart transplant recipients make of their quality of life.

E. CONCLUSION

Preliminary conclusions can be reached based on the results presented above, although more striking conclusions are stated in Chapter 26 based on the comparative analyses. Our results suggest the following: (1) Overall, the objective quality of life of heart transplant recipients is substantially compromised. (2) However, on the basis of subjective quality of life indicators, they are found to do remarkably well. In short, heart transplant recipients subjectively rate their quality of life high. The inconsistency in these findings is not surprising. In our previous research on kidney dialysis and kidney transplant patients our results have been similar (Evans et al., 1984).

Our summary conclusion has been noted in the introduction to this Chapter: Humans are remarkably resilient. They adapt to their social environment in much the same way they adapt to their physical environment. Rene Dubos (1965) has commented on this adaptability as follows:

> The response that a particular person makes to a given situation is conditioned by his past; his evolutionary and experiential backgrounds sharply delimit the range of conditions within which his responses can be successful. But experience shows that human beings are

> not passive components in adaptive systems. Their responses commonly manifest themselves as acts of personal creation. Each individual person tries to achieve some self-selected end even while he is responding to stimuli and adapting to them.

Dubo's entire treatise, Man Adapting, is an acknowledgement that human beings are resilient and are able to adapt both physically and socially. The fact that heart transplant recipients have a high subjective quality of life and a low objective quality of life underscores the manner in which adaptability can be expressed. This should not be surprising, as the history of mankind is well-sprinkled with exemplary individuals who have been able to overcome marked physical disability in a struggle against all odds. Heart transplant recipients, previously at death's door, appear to be locked in the same struggle against physical and psychosocial adversity. To conclude they have failed in this struggle is a conclusion devoid of merit.

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CHAPTER 26

A COMPARATIVE ANALYSIS OF QUALITY OF LIFE: HEART TRANSPLANTATION, KIDNEY TRANSPLANTATION, KIDNEY DIALYSIS, AND THE GENERAL POPULATION

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A. INTRODUCTION

Without some standard for comparison, it is difficult to interpret the quality of life indicators for heart transplant recipients, as reported in Chapter 25. The primary objective of the analyses undertaken in this chapter is to provide a basis for such a comparison. To accomplish this, we compare the quality of life of heart transplant recipients with that of kidney dialysis and kidney transplant patients. Also, to provide greater perspective on selected measures, the quality of life of heart transplant recipients is compared with that of the general population. The comparisons with the general population function as essentially the "norms" of comparison. This is not to say that heart transplant, kidney transplant, and renal dialysis patients should be on equal footing with the general population with regard to quality of life. In fact, perhaps the most appropriate quality of life comparison is between heart transplant and kidney transplant recipients. Elsewhere we have shown that renal dialysis patients, regardless of dialysis type, have a quality of life substantially below that of kidney transplant recipients (Evans et al., 1984). Nonetheless, still another view of quality of life is needed. The general population comparisons provided in this chapter enable us to better understand the extent to which people undergoing a significant medical intervention are able to adapt to their life circumstances.

Unfortunately there have been few attempts to comparatively assess the quality of life of individuals who have undergone various life-saving medical interventions. Some would argue, perhaps with merit, that such comparisons lack an absolute standard against which deviation

can be measured. Others would argue that such a standard is allusive and that quality of life varies considerably among patients with different lifesaving interventions. Still others are convinced that quality of life is so subjective that any attempt to measure it is necessarily fruitless. While each of these criticisms has some merit, we reject the notion that comparative quality of life assessments cannot be performed meaningfully.

Over the course of the past three years, we have endeavored to demonstrate the feasibility of comparative quality of life assessments. We will now show how, despite considerable adversity, that such assessments of quality of life are extremely meaningful, not only from the patient's perspective, but from that of the clinicians responsible for the care of the patients. In addition, these results are of interest to policymakers who are increasingly being asked to deliberate in the making of "hard choices." In effect, we feel the results we present here are of considerable help in the provision of patient care and are fundamentally essential to the promulgation of sound public health policy. These analyses represent the state-of-the-art in an area that will grow in importance over the next several decades. If the analyses appear overly simplistic, they represent little more than the crude tools and methodology currently available to accomplish an extraordinarily complex and controversial task.

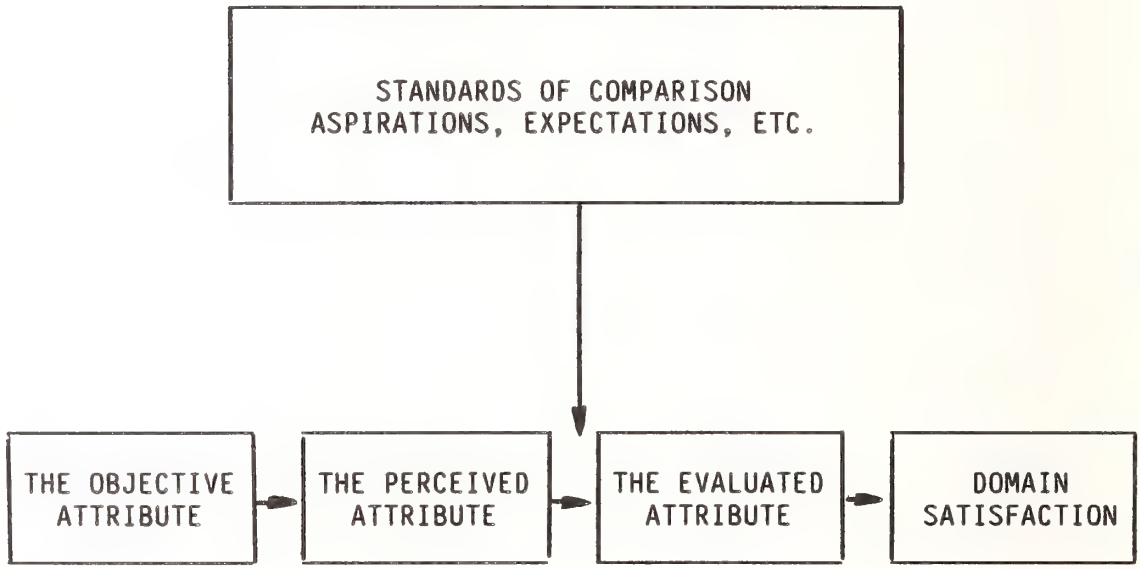
B. CONCEPTUAL MODEL

In Chapter 23 we borrowed from the work of Campbell et al. (1976) and presented a model for the assessment of quality of life. This

model essentially showed how individuals independently evaluate their quality of life. It was argued, for example, that people live in an objectively defined environment, but they perceive a subjectively defined environment and it is this psychological "life space," as Campbell and associates (1976:13) refer to it, that people respond to. Figure 26-1 is a simplified version of the model we have previously presented in Chapter 23. While this model is very useful for the conceptualization of the process by which people come to express a given level of satisfaction with their lives, it is not completely suitable for conceptualizing the factors that lead to a particular expression of life satisfaction. Thus, in the case of patients undergoing medical intervention, we would like to propose a simple model for the assessment of quality of life outcomes.

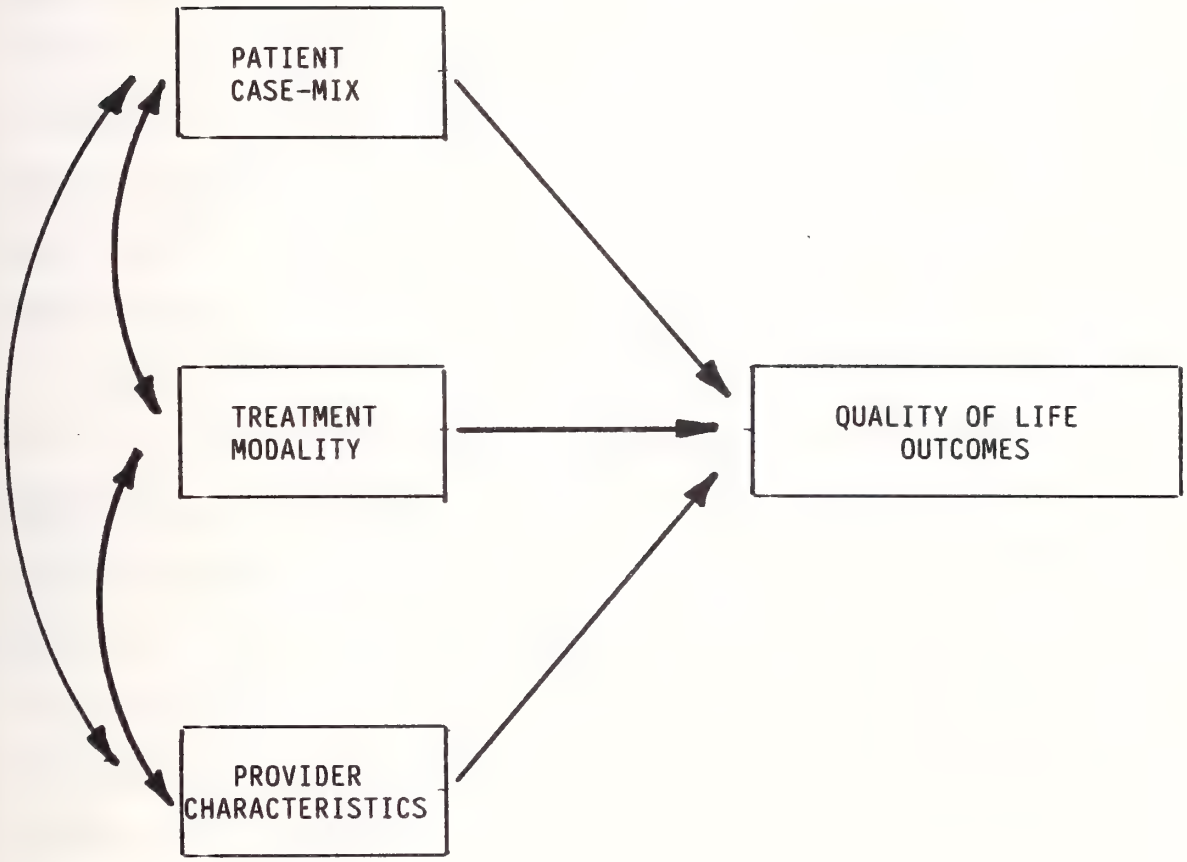
Quality of life outcomes for persons receiving medical treatment can be envisioned as a function of at least three factors. They are: (1) patient case-mix (some patients are older and sicker than others), (2) treatment modality (when more than one treatment modality is available, patients on one modality may do better than those on others), and (3) provider characteristics (some providers are known to provide a better level of care than others). Figure 26-2 depicts the causal relationships among these variables but also reveals a correlation among patient case-mix and treatment modality. In effect, we are suggesting that when multiple treatment modalities are available, as in the case of end-stage renal disease (ESRD), some patients have characteristics that preclude the use of certain modalities. Also, some providers may be inclined to use certain

Figure 26-1
Basic Model of the Relationship Between Objective Environmental Characteristics and the Experienced Level of Satisfaction With A Life Domain



SOURCE: Campbell et al., 1976:13.

Figure 26-2
Factors Affecting Quality of Life Outcomes Associated
With Medical Interventions



treatment modalities rather than others. The general outcome model, although simplistically represented in Figure 26-2, is very complex.

C. DATA

The data for the analyses presented in this chapter have been derived from two separate studies--the National Heart Transplantation Study (NHTS) and the National Kidney Dialysis and Kidney Transplantation Study (NKDKTS). Both studies were conducted nearly simultaneously, with primary data collection for the NKDKTS being completed about one year before that of the NHTS. Very similar if not exactly the same data were collected in both studies. The data for both studies are described briefly below.

1. THE NATIONAL HEART TRANSPLANTATION STUDY DATA

It is unnecessary here to describe in detail the data for the National Heart Transplantation Study. These data have been fully described in Chapters 5, 6, and 7 of this report. The majority of the results presented here were obtained from our survey of 152 living heart transplant recipients. In addition, some of the data were extracted from the medical records for these patients. Our survey constituted a patient census for each of the six heart transplant centers that participated in the National Heart Transplantation Study.

2. THE NATIONAL KIDNEY DIALYSIS AND KIDNEY TRANSPLANTATION STUDY DATA

Data for the NKDKTS were obtained by a survey of 859 patients from eleven dialysis and transplant centers in the U.S. (Evans et al., 1984). Two-stage sampling was used to select a purposive sample of

dialysis and transplant centers and a probability sample of dialysis and transplant patients (Kish, 1965). First, a purposive sample of centers was selected to maximize variation with respect to geographical distribution, size and type of facility, academic affiliation, ownership, availability of a home dialysis training program, number of patients by treatment modality, and the urban/rural nature of the service area. Second, a random probability sample of patients stratified by treatment modality at the time of study (home hemodialysis, in-center hemodialysis, continuous ambulatory peritoneal dialysis (CAPD)/continuous cycling peritoneal dialysis (CCPD), and transplantation) was drawn from each facility.

All continuous peritoneal dialysis (CPD) patients at the eleven centers were included in the study, and samples of home hemodialysis, in-center hemodialysis, and transplant patients with functioning grafts were randomly selected from the population of patients at each center. All patients were 18 years of age or older. Of the 859 patients interviewed, 287 were on home hemodialysis, 347 were on in-center hemodialysis, 81 were continuous peritoneal dialysis patients, and 144 were transplanted (74 with a living related donor and 70 with a cadaver donor transplant).

It is noteworthy that direct inference of the study results to the general dialysis and transplant population was not possible given this sample design. A national probability sample survey would be required to make such inferences, but such a study is unlikely to be undertaken because of the cost and logistical problems of such an undertaking.

Data were collected from patients, medical records, and from a health care professional familiar with each patient's functional status. Information on sociodemographic and medical variables, employment status, and subjective indicators of quality of life were obtained from the patient during a personal interview. With consent, medical information was abstracted from the medical record. In addition, a nephrologist, transplant surgeon, social worker, or nurse familiar with the patient's functional status recorded specific comorbid conditions and the extent to which physical activity was limited.

To insure that the data acquired were of high quality, persons responsible for collection of the study data underwent an intense three-day training session in Seattle prior to initiation of data collection activities. Uniform study procedures were followed at each center. Each data collector was provided with an extensive procedures manual which included question-by-question specifications for all data items contained in each of the data collection instruments (Evans et al., 1982). Routine contact was made on a weekly basis with all data collectors.

The overall response rate for the two major patient-related data collection instruments was excellent. Completed patient interviews and medical records abstraction forms were obtained for 90 percent of the patients ultimately considered eligible for the study.

D. VARIABLES

In Chapters 23 and 25 we have described at some length our various measures of quality of life. We will, once again, highlight that discussion insofar that we must make it possible to meaningfully interpret the findings that are presented here. For more complete discussion of each of the measures, and for a copy of the exact questions asked to ascertain quality of life, the reader is referred to Chapter 23.

1. OBJECTIVE QUALITY OF LIFE INDICATORS

The Karnofsky Index was used as an overall indicator of functional impairment and is a measure of physical functional status ranging from 1 (normal, no complaints; no evidence of disease) to 10 (moribund; fatal processes progressing rapidly). The Karnofsky Index is displayed in Table 26-1.

A patient's ability to work was ascertained by asking the following simple question: "Are you now able to work for pay full-time, part-time, or not at all?" While it could be argued that ability to work is more subjective than objective, a correlation analysis does not support this.

Health status was ascertained using the Sickness Impact Profile (SIP). The SIP is a standardized questionnaire that measures sickness-related dysfunction. The SIP consists of 136 questions which are grouped in 12 categories (see Table 26-2), each describing an area of activity in which dysfunctional behavior may occur. A score for each of the categories may be calculated, as well as a psychosocial dimension score, a physical dimension score, and an overall SIP

Table 26-1
Karnofsky Performance Status Index

Condition	Performance Status %	Comments
A. Able to carry on normal activity and to work. No special care is needed.	100	Normal. No complaints. No evidence of disease.
	90	Able to carry on normal activity. Minor signs or symptoms of disease.
	80	Normal activity with effort. Some signs or symptoms of disease.
B. Unable to work. Able to live at home, care for most personal needs. A varying degree of assistance is needed.	70	Cares for self. Unable to carry on normal activity or to do active work.
	60	Requires occasional assistance, but is able to care for most of his/her needs.
	50	Requires considerable assistance and frequent medical care.
C. Unable to care for self. Requires equivalent of institutional or hospital care. Disease may be progressing rapidly.	40	Disabled. Requires special care and assistance. Severely disabled. Hospitalization is indicated although death is not imminent.
	20	Hospitalization necessary, very sick, active supportive treatment necessary.
	10	Moribund. Fatal processes progressing rapidly.
	0	Dead.

(See Karnofsky and Burchenal, 1949; Hutchinson et al., 1979; Gutman et al., 1981.)

Table 26-2
Categories and Sample Items From the Sickness Impact Profile

Category	Items Describing Behavior Related to	Selected Items
SR	Sleep and Rest	I sit during much of the day. I sleep or nap during the day.
E	Eating	I am eating no food at all, nutrition is taken through tubes or intravenous fluids. I am eating special or different food.
W	Work	I am not working at all. I often act irritable toward my work associates.
HM	Home Management	I am not doing any of the maintenance or repair work around the house that I usually do. I am not doing heavy work around the house.
RP	Recreation and Pastimes	I am going out for entertainment less. I am not doing any of my usual physical recreation or activities.
A	Ambulation	I walk shorter distances or stop to rest often. I do not walk at all.
M	Mobility	I stay within one room. I stay away from home only for brief periods of time.
BCM	Body Care and Movement	I do not bathe myself at all, but am bathed by someone else. I am very clumsy in body movements.

Table 26-2 (Continued)
Categories and Sample Items From the Sickness Impact Profile

Category	Items Describing Behavior Related to	Selected Items
SI	Social Interaction	I am doing fewer social activities with groups of people. I isolate myself as much as I can from the rest of the family.
AB	Alertness Behavior	I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things. I sometimes behave as if I were confused or disoriented in place or time, for example, where I am, who is around, directions, what day it is.
EB	Emotional Behavior	I laugh or cry suddenly. I act irritable and impatient with myself, for example, talk badly about myself, swear at myself, blame myself for things that happen.
C	Communication	I am having trouble writing or typing. I do not speak clearly when I am under stress.

(See Gilson et al., 1979.)

score. In this regard, the SIP actually combines both an objective and subjective aspect of quality of life. Total SIP scores range from 1 to 100 where a high score indicates poor health status and a low score indicates good health. As the level of dysfunction experienced by the subject rises, so does the SIP score (Bergner et al., 1981; 1984; Pollard et al., 1976; Bergner et al., 1976).

2. SUBJECTIVE QUALITY OF LIFE INDICATORS

The subjective indicators of quality of life include the Index of Psychological Affect, the Index of Overall Life Satisfaction, and the Index of Well-Being (Campbell et al., 1976; Campbell and Converse, 1980). The Index of Psychological Affect, based on eight bipolar items, describes how patients feel about their present life, and responses are averaged for a mean score. The Index of Overall Life Satisfaction is also based on bipolar responses. The Index of Well-Being is calculated by combining the Index of Overall Life Satisfaction and the Index of Psychological Affect (giving slightly more weight to the former).

Both the Index of Psychological Affect and the Index of Overall Life Satisfaction range from a low of 1.0 (completely dissatisfied) to a high of 7.0 (completely satisfied). The Index of Well-Being ranges between 2.1 and 14.7, where a score of 2.1 indicates low well-being and a score of 14.7 indicates high well-being.

E. STATISTICAL METHODS

All statistics presented in this chapter, as in Chapter 25, are descriptive. Statistical averages (means) and standard deviations are

presented for six patient groups and, when available, the general population. The patient groups are as follows:

- heart transplant recipients
- kidney transplant recipients
- home hemodialysis patients
- in-center hemodialysis patients
- continuous peritoneal dialysis patients
- all dialysis patients combined

The last category contains the home hemodialysis, in-center hemodialysis, and continuous peritoneal dialysis patients. At this stage of the analysis we have not attempted to ascertain whether the differences in quality of life scores among various patient groups or the general population are statistically significant. The issue, however, is not always whether the differences are statistically significant but, rather, whether they are substantively important. Future analyses must be undertaken to address both of these important issues.

F. RESULTS

The results reported here have been arranged into three categories. They are as follows: (1) a comparison of the sociodemographic characteristics of all patient groups, (2) descriptive frequency distributions for all quality of life indicators, and (3) a comparison of summary scores on all quality of life indicators.

1. SOCIODEMOGRAPHIC CHARACTERISTICS

Table 26-3 summarizes the sociodemographic characteristics of all patient groups included in these analyses. As indicated, there are substantial differences in the sociodemographic composition of the various patient groups. As noted in our discussion of the patient quality of life outcome model, these differences may have an affect on how patients assess their quality of life. It may be these differences rather than the type of treatment patients are receiving that account for any observed differences in quality of life. We should note that in our previous analyses of the kidney dialysis and kidney transplant patients we found these differences in sociodemographic composition to be statistically important (Evans et al., 1984). However, when these differences were controlled for statistically, we found that treatment modality continued to exercise an independent effect on patient quality of life outcomes. Similar analyses would be required to ascertain the importance of the sociodemographic differences shown in Table 26-3 for heart transplant recipients compared with other patient groups.

2. DESCRIPTIVE FREQUENCY DISTRIBUTIONS FOR ALL QUALITY OF LIFE INDICATORS

We begin our discussion of the specific quality of life indicators by examining the distribution of responses across all values of each indicator. Table 26-4 displays the results for the Karnofsky Index. As shown here, a much higher percentage of heart transplant recipients have been reported "normal" by persons responsible for their care. Two-thirds of the heart transplant recipients are considered to have "no evidence of disease," compared

Table 26-3
Sociodemographic Characteristics of All Patient Groups

SOCIODEMOGRAPHIC CHARACTERISTICS	PATIENT GROUP					
	HEART TRANSPLANT RECIPIENTS	KIDNEY TRANSPLANT RECIPIENTS	HOME HEMODIALYSIS PATIENTS	IN-CENTER HEMODIALYSIS PATIENTS	CONTINUOUS PERITONEAL DIALYSIS PATIENTS	ALL DIALYSIS PATIENTS
AGE ($\bar{X}$)	42.38	37.15	47.02	51.92	49.80	49.7
SEX						
MALE (%)	87.5	56.3	64.1	50.0	45.7	55.2
FEMALE (%)	12.5	43.8	35.9	50.0	54.3	44.8
RACE						
BLACK (%)	3.3	11.8	8.7	42.5	9.9	25.2
WHITE (%)	87.5	84.7	86.4	53.5	84.0	70.2
OTHER (%)	9.2	3.5	4.9	4.0	6.2	4.6

Table 26-4
Frequency Distribution for the Karnofsky Index
(Expressed as a Percent)

KARNOFSKY INDEX CATEGORY	PATIENT GROUP					
	HEART TRANSPLANT RECIPIENTS	KIDNEY TRANSPLANT RECIPIENTS	HOME HEMODIALYSIS PATIENTS	IN-CENTER HEMODIALYSIS PATIENTS	CONTINUOUS PERITONEAL DIALYSIS PATIENTS	ALL DIALYSIS PATIENTS
NORMAL: NO COMPLAINTS: NO EVIDENCE OF DISEASE	66.3	47.8	12.8	8.4	2.5	9.5
ABLE TO CARRY ON NORMAL ACTIVITY: MINOR SIGNS AND SYMPTOMS OF DISEASE	23.2	31.3	46.3	36.3	45.0	41.4
NORMAL ACTIVITY WITH EFFORT: SOME SIGNS AND SYMPTOMS OF DISEASE	6.1	9.0	25.3	25.2	25.0	25.2
CARE FOR SELF: UNABLE TO CARRY ON NORMAL ACTIVITY OR DO ACTIVE WORK	0.6	4.5	8.9	12.3	12.5	11.0
REQUIRES OCCASIONAL ASSISTANCE BUT IS ABLE TO CARE FOR MOST OF OWN NEEDS	2.8	3.7	3.6	7.2	8.8	5.9
REQUIRES CONSIDERABLE ASSISTANCE AND FREQUENT MEDICAL CARE	1.1	3.7	1.4	4.5	3.7	3.2
DISABLED: REQUIRES SPECIAL CARE AND ASSISTANCE	0.0	0.0	1.8	6.0	2.5	3.9
SEVERELY DISABLED: HOSPITALIZATION IS INDICATED ALTHOUGH DEATH NOT IMMINENT	0.0	0.0	0.0	0.0	0.0	0.0
VERY SICK: HOSPITALIZATION NECESSARY	0.0	0.0	0.0	0.0	0.0	0.0
MORIBUND: FATAL PROCESSES PROGRESSING RAPIDLY	0.0	0.0	0.0	0.0	0.0	0.0

with 47.8 percent of the kidney transplant recipients, 12.8 percent of the home hemodialysis patients, 8.4 percent of the in-center hemodialysis patients, and 2.5 percent of the continuous peritoneal dialysis patients. Clearly on this indicator of functional impairment, heart transplant recipients are less impaired than any other patient group with which they are compared.

Table 26-5 shows the responses to the question concerning ability to work. While heart transplant recipients may be less functionally impaired than any other patient group, this does not appear to translate into a greater ability to work. Thirty-four percent of the heart transplant recipients said they were able to work full-time, 24.7 percent said part-time, and 41.3 percent indicated that they were unable to work. The comparable results for the other patient groups are shown in Table 26-5. Clearly, kidney transplant recipients have a greater ability to work than all patient groups. Even home hemodialysis patients indicate that they are more able to work than heart transplant recipients.

Table 26-6 shows a frequency distribution of overall scores on the Sickness Impact Profile, a standardized measurement which is sensitive to the multidimensional nature of functional status (Bergner et al., 1984). Once again, as shown here, heart transplant recipients have overall scores that are well below those of kidney transplant recipients suggesting that heart transplant recipients have poorer overall health status and greater functional impairment than kidney transplant recipients. However, when compared with hemodialysis patients, heart transplant recipients are similar to home hemodialysis

Table 26-5
Ability to Work Among Different Patient Groups
(Expressed As A Percent)

PATIENT GROUP	ABILITY TO WORK			NUMBER OF PATIENTS
	FULL-TIME	PART-TIME	NOT AT ALL	
Heart Transplant Recipients	34.0	24.7	41.3	152
Kidney Transplant Recipients	60.1	14.0	25.9	143
Home Hemodialysis Patients	30.5	28.8	40.7	285
In-Center Hemodialysis Patients	16.2	20.9	62.8	339
Continuous Peritoneal Dialysis Patients	13.6	11.1	75.3	81
All Dialysis Patients	21.7	23.0	55.3	705

Table 26-6
Frequency Distributions for the Sickness Impact Profile[1]
(Expressed As A Percent)

	PATIENT GROUP					
OVERALL SIP SCORE	HEART TRANSPLANT RECIPIENTS	KIDNEY TRANSPLANT RECIPIENTS	HOME HEMODIALYSIS PATIENTS	IN-CENTER HEMODIALYSIS PATIENTS	CONTINUOUS PERITONEAL DIALYSIS PATIENTS	ALL DIALYSIS PATIENTS
0 - 4	34.9	61.8	38.1	22.6	17.3	28.3
5 - 9	30.2	20.1	25.2	22.0	23.5	23.4
10 - 14	12.1	8.3	17.1	18.7	23.5	18.6
15 - 19	11.4	4.2	7.7	12.8	13.6	10.8
20 - 24	6.7	2.1	5.6	9.5	11.1	8.1
25 - 29	2.0	2.8	2.1	5.3	4.9	4.0
30 - 34	1.3	0.0	2.4	2.7	0.0	2.3
35 - 39	0.7	0.7	1.0	2.1	3.7	1.8
40 - 44	0.0	0.0	0.0	2.7	2.5	1.8
45 - 49	0.0	0.0	0.0	0.9	0.0	0.4
50 - 100	0.0	0.0	0.7	0.9	0.0	0.4

[1]Includes all patients regardless of length of time since transplant or onset of dialysis.

patients and are actually in better health than in-center hemodialysis and continuous peritoneal dialysis patients.

Table 26-7 shows greater detail on the various subscales of the Sickness Impact Profile for all patient groups. Clearly there is considerable variation among all patient groups with regard to the various subscales of the SIP. On every subscale, heart transplant recipients do worse than kidney transplant recipients, but on all but one subscale are superior to in-center hemodialysis patients.

The results on the subjective indicators of quality of life differ greatly from those on the objective indicators. This, of course, was reported in Chapter 25. Nearly all patient groups compare well with the general population on the various subjective quality of life indicators. In Table 26-8, for example, the percentage distribution for each patient group on the Index of Well-Being is shown. As the descriptive statistics reveal, kidney transplant recipients report the highest level of well-being, followed by the home hemodialysis patients, and then the heart transplant recipients. The kidney transplant recipients actually report a level of well-being that exceeds that of the general population. It is noteworthy, however, that none of the subjective quality of life index scores have been adjusted to take age, sex, and racial differences into account, that is, all scores are unadjusted. Nonetheless, of the various patient groups, in-center hemodialysis patients report the lowest overall level of well-being.

With regards to psychological affect, that is, how positively patients view themselves, we find that, once again, kidney transplant

Table 26-7
Subscale Scores On The Sickness Impact Profile
For All Patient Groups

DIMENSION OF SIP		PATIENT GROUP					
		HEART TRANSPLANT RECIPIENTS	KIDNEY TRANSPLANT RECIPIENTS	HOME HEMODIALYSIS PATIENTS	IN-CENTER HEMODIALYSIS PATIENTS	CONTINUOUS PERITONEAL DIALYSIS PATIENTS	ALL DIALYSIS PATIENTS
SLEEP AND REST	$\bar{X}$	13.29	6.79	16.37	21.96	22.23	19.61
	S.E.	(1.50)	(1.23)	(1..32)	(1.44)	(4.47)	(.98)
EMOTIONAL BEHAVIOR	$\bar{X}$	8.65	5.52	8.04	8.56	10.28	8.46
	S.E.	(1.13)	(1.18)	(.92)	(.91)	(3.00)	(.64)
BODY CARE AND MOVEMENT	$\bar{X}$	3.77	2.36	5.25	7.71	8.02	6.69
	S.E.	(.64)	(.49)	(.71)	(.73)	(1.71)	(.49)
HOME MANAGEMENT	$\bar{X}$	10.92	7.13	15.58	23.62	18.57	19.87
	S.E.	(1.62)	(1.22)	(1.18)	(1.38)	(2.92)	(.90)
MOBILITY	$\bar{X}$	4.12	2.49	5.55	10.50	7.54	8.20
	S.E.	(.80)	(.62)	(.83)	(1.03)	(1.93)	(.65)
SOCIAL INTERACTION	$\bar{X}$	10.60	4.37	7.52	11.31	6.66	9.38
	S.E.	(1.37)	(.82)	(.66)	(.81)	(1.27)	(.51)
AMBULATION	$\bar{X}$	7.46	6.18	11.86	16.05	13.89	14.21
	S.E.	(1.12)	(1.03)	(.91)	(.92)	(2.27)	(.63)
ALERTNESS BEHAVIOR	$\bar{X}$	12.12	5.19	6.81	11.82	6.41	9.32
	S.E.	(1.81)	(1.22)	(.89)	(1.21)	(1.82)	(.74)
COMMUNICATION	$\bar{X}$	4.07	1.46	2.72	5.68	2.76	4.22
	S.E.	(1.20)	(.50)	(.54)	(.65)	(1.17)	(.41)
WORK	$\bar{X}$	39.88	26.73	39.06	44.88	54.14	43.05
	S.E.	(3.15)	(3.09)	(2.18)	(1.99)	(4.82)	(1.42)
RECREATION-PASTIMES	$\bar{X}$	18.52	9.51	19.05	23.97	22.39	21.77
	S.E.	(1.89)	(1.59)	(1.33)	(1.35)	(3.54)	(.92)
EATING	$\bar{X}$	4.63	2.74	8.12	10.20	6.05	9.03
	S.E.	(.49)	(.38)	(.45)	(.42)	(1.10)	(.30)
PHYSICAL DIMENSION	$\bar{X}$	4.71	3.29	6.87	10.27	9.31	8.67
	S.E.	(.69)	(.57)	(.70)	(.74)	(1.58)	(.50)
PSYCHOSOCIAL DIMENSION	$\bar{X}$	9.25	4.19	6.52	9.80	6.53	8.18
	S.E.	(1.05)	(.71)	(.59)	(.72)	(1.28)	(.46)
TOTAL SIP	$\bar{X}$	9.60	5.47	10.05	13.92	12.18	12.16
	S.E.	(.86)	(.65)	(.64)	(.68)	(1.44)	(.46)
NUMBER OF CASES		110	116	227	272	37	536

Table 26-8
The Index of Well-Being: Percentage Distribution of Responses and Descriptive Statistics

INDEX OF WELL-BEING SCORE	PATIENT GROUP						
	HEART TRANSPLANT RECIPIENTS	KIDNEY TRANSPLANT RECIPIENTS	HOME HEMODIALYSIS PATIENTS	IN-CENTER HEMODIALYSIS PATIENTS	CONTINUOUS PERITONEAL DIALYSIS PATIENTS	ALL DIALYSIS PATIENTS	GENERAL[1] POPULATION
2.10 - 7.04	7.9	6.3	8.0	9.3	12.3	9.1	3.9
7.05 - 9.04	15.1	9.0	13.9	16.2	9.9	14.6	7.4
9.05 - 10.04	5.9	9.0	8.4	11.0	8.6	9.7	7.7
10.05 - 10.54	5.9	4.2	4.9	5.5	6.2	5.3	5.2
10.55 - 11.04	9.9	3.5	8.4	6.7	4.9	7.2	7.2
11.05 - 11.54	9.9	3.5	8.0	6.4	4.9	6.9	7.1
11.55 - 12.04	3.3	6.3	6.3	7.2	8.6	7.0	7.9
12.05 - 12.54	7.9	9.0	7.0	7.8	7.4	7.4	11.1
12.55 - 13.04	9.2	12.5	8.7	7.0	9.9	8.0	11.5
13.05 - 13.54	6.6	6.3	6.6	6.7	6.2	6.6	10.2
13.55 - 14.04	6.6	6.3	4.9	5.2	7.4	5.3	6.9
14.05 - 14.54	2.0	8.3	6.3	4.9	4.9	5.5	5.8
14.55 - 14.70	9.9	16.0	8.7	6.1	8.6	7.4	8.1
TOTAL	100.0	100.0	100.0	100.0	100.0	100.0	100.0
DESCRIPTIVE STATISTICS							
MEAN	11.113	11.834	11.122	10.767	11.050	10.942	11.768
STANDARD DEVIATION	2.534	2.609	2.667	2.731	2.839	2.719	2.207
RANGE (POSSIBLE SCORES)	2.1-14.7	2.1-14.7	2.1-14.7	2.1-14.7	2.1-14.7	2.1-14.7	2.1-14.7
N	152	144	287	345	81	713	2,160

[1]SOURCE: Campbell et al., 1976:46.

recipients have the highest score, followed by heart transplant recipients, and home hemodialysis patients (see Table 26-9). In-center hemodialysis patients report the lowest overall level of psychological affect.

Finally, on our measure of overall life satisfaction, kidney transplant patients, on still another measure surpass all other patient groups (see Table 26-10). In fact, they once again have a score above that of the general population. Surprisingly, however, of the various patient groups, kidney transplant recipients are followed by continuous peritoneal dialysis patients, then home hemodialysis patients, and then heart transplant recipients in terms of life satisfaction.

3. COMPARISON OF SUMMARY SCORES ON ALL QUALITY OF LIFE INDICATORS

As in Chapter 25, to summarize the results of our analyses of quality of life, a mean or average score and a standard deviation has been computed for each indicator. These scores are shown in Table 26-11. All the results displayed in this table have just been discussed above. As noted, with the exception of the Karnofsky Index, kidney transplant recipients reported a quality of life that surpassed the other patient groups, although we have not examined the statistical significance of these differences. On many indicators, heart transplant recipients were very comparable with home hemodialysis patients and on all indicators with the exception of ability to work they equaled or surpassed in-center hemodialysis patients. Moreover, on all indicators but life satisfaction they surpassed continuous peritoneal dialysis patients.

Table 26-9
The Index of Psychological Affect:
Percentage Distribution of Responses and Descriptive Statistics

INDEX OF PSYCHOLOGICAL AFFECT SCORE	PATIENT GROUP						
	HEART TRANSPLANT RECIPIENTS	KIDNEY TRANSPLANT RECIPIENTS	HOME HEMODIALYSIS PATIENTS	IN-CENTER HEMODIALYSIS PATIENTS	CONTINUOUS PERITONEAL DIALYSIS PATIENTS	ALL DIALYSIS PATIENTS	GENERAL[1] POPULATION
1.00 - 1.94	.7	.7	.7	2.1	0.0	1.3	0.6
1.95 - 2.94	4.6	1.4	3.9	3.9	6.4	4.2	1.6
2.95 - 3.94	9.9	5.6	6.8	11.3	10.3	9.3	5.6
3.95 - 4.44	8.6	9.1	8.5	10.4	7.7	9.3	6.8
4.45 - 4.94	7.9	11.2	9.6	12.5	9.0	10.9	8.6
4.95 - 5.24	4.6	4.9	7.1	5.3	12.8	6.9	6.1
5.25 - 5.44	3.9	7.0	5.7	8.3	9.0	7.3	6.2
5.45 - 5.74	9.2	7.0	11.0	8.6	1.3	8.8	7.3
5.75 - 5.94	3.3	5.6	6.4	6.2	7.7	6.5	8.7
5.95 - 6.24	7.2	8.4	7.1	6.5	14.1	7.6	9.7
6.25 - 6.44	11.2	7.7	11.4	6.2	3.8	8.0	9.7
6.45 - 6.74	7.2	9.1	7.1	6.5	6.4	6.8	9.9
6.75 - 7.00	21.7	22.4	14.6	12.2	11.5	13.1	19.2
TOTAL	100.0	100.0	100.0	100.0	100.0	100.0	100.0
DESCRIPTIVE STATISTICS							
MEAN	5.490	5.620	5.421	5.155	5.236	5.271	5.675
STANDARD DEVIATION	1.319	1.163	1.200	1.307	1.261	1.264	1.115
RANGE (POSSIBLE SCORES)	1.0-7.0	1.0-7.0	1.0-7.0	1.0-7.0	1.0-7.0	1 .0-7.0	1.0-7.0
N	152	143	281	337	78	696	2,147

[1]SOURCE: Campbell et al., 1976:46.

Table 26-10
The Overall Life Satisfaction Variable:
Percentage Distribution of Responses and Descriptive Statistics

	PATIENT GROUP						
OVERALL LIFE SATISFACTION	HEART TRANSPLANT RECIPIENTS	KIDNEY TRANSPLANT RECIPIENTS	HOME HEMODIALYSIS PATIENTS	IN-CENTER HEMODIALYSIS PATIENTS	CONTINUOUS PERITONEAL DIALYSIS PATIENTS	ALL DIALYSIS PATIENTS	GENERAL[1] POPULATION
COMPLETELY DISSATISFIED	.7	2.1	4.2	5.0	4.9	4.7	0.9
VERY DISSATISFIED	1.3	3.5	1.7	4.7	2.5	3.2	2.1
DISSATISFIED	11.8	2.1	5.9	6.4	6.2	6.2	3.7
NEUTRAL	12.5	12.6	18.9	16.4	16.0	17.3	11.3
SATISFIED	33.6	15.4	21.3	18.1	16.0	19.2	20.7
VERY SATISFIED	26.3	26.6	24.1	24.9	23.5	24.4	39.6
COMPLETELY SATISFIED	13.8	37.8	23.8	24.6	30.9	25.0	21.7
DESCRIPTIVE STATISTICS							
MEAN	5.112	5.664	5.189	5.108	5.296	5.162	5.544
STANDARD DEVIATION	1.279	1.487	1.556	1.693	1.684	1.637	1.250
RANGE (POSSIBLE SCORES)	1.0-7.0	1.0-7.0	1.0-7.0	1.0-7.0	1.0-7.0	1.0-7.0	1.0-7.0
N	152	143	286	342	81	709	2,134

[1] SOURCE: Campbell et al., 1976:46

Table 26-11
Summary of Quality of Life Scores For All Patient Groups

PATIENT GROUP		UNADJUSTED OBJECTIVE INDICATORS OF QUALITY OF LIFE			UNADJUSTED SUBJECTIVE INDICATORS OF QUALITY OF LIFE		
		FUNCTIONAL IMPAIRMENT[1]	ABILITY TO WORK[2]	HEALTH STATUS[3]	WELL-BEING[4]	PSYCHOLOGICAL AFFECT[5]	LIFE SATISFACTION[6]
HEART TRANSPLANT RECIPIENTS	$\bar{X}$	1.47	57.88	9.60	11.11	5.49	5.11
	S.D.	(.772)	(49.55)	(9.01)	(2.53)	(1.32)	(1.28)
KIDNEY TRANSPLANT RECIPIENTS	$\bar{X}$	1.96	74.13	5.52	11.83	5.62	5.66
	S.D.	(1.30)	(43.95)	(7.06)	(2.72)	(1.25)	(1.62)
HOME HEMODIALYSIS PATIENTS	$\bar{X}$	2.56	59.30	9.53	11.12	5.42	5.19
	S.D.	(1.19)	(49.21)	(9.13)	(2.67)	(1.20)	(1.56)
IN-CENTER HEMODIALYSIS PATIENTS	$\bar{X}$	3.11	37.20	13.89	10.77	5.15	5.11
	S.D.	(1.57)	(48.40)	(11.24)	(2.73)	(1.31)	(1.69)
CONTINUOUS PERITONEAL DIALYSIS PATIENTS	$\bar{X}$	3.01	24.69	13.69	11.05	5.24	5.30
	S.D.	(1.34)	(43.39)	(9.71)	(2.83)	(1.26)	(1.68)
ALL DIALYSIS PATIENTS	$\bar{X}$	2.88	44.68	12.16	10.94	5.27	5.16
	S.D.	(1.43)	(49.75)	(10.54)	(2.72)	(1.26)	(1.64)
GENERAL POPULATION	$\bar{X}$	N/A	N/A	N/A	11.77	5.68	5.45
	S.D.	N/A	N/A	N/A	(2.21)	(1.12)	(1.25)

[1]Based on the Karnofsky Index, range of values = 1.0 to 10.0 where 1.0 = absence of dysfunction and 10 = maximum dysfunction (death).

[2]Ability to work, range of values = 0.0 - 100.0, where 0.0 = patients unable and 100.0 = patients able.

[3]Total Sickness Impact Profile score only, range of values = 0.0 - 100.0. Lower scores indicate better health status.

[4]Range of values = 2.1 to 14.7 where high score = positive well-being.

[5]Range of values = 1.0 to 7.0 where 7.0 = positive affect.

[6]Range of values = 1.0 to 7.0 where 7.0 = positive satisfaction.

Of these results, those concerning objective quality of life are the least surprising. Clearly, patients with compromised health status have problems working and functioning that are uncommon among people in good health. What is surprising, however, is how highly all patients rate their subjective quality of life. As discussed in Chapter 25, this likely owes to the remarkable ability of humans to adapt to adverse circumstances, including those individuals whose lives have been seriously threatened by disease.

G. CONCLUSION

As noted in Chapter 25, it is not expected that all people will readily accept the results presented here. Some will argue that the entire exercise of quality of life assessment is meaningless. Others will be suspicious of the results declaring that in no way can a person who is in ill health possibly rate their quality of life as high as the patients studied here. We disagree. Once again, a citation from Dubos (1965:xviii-xix) is particularly appropriate.

> The components of the body machine react with the environment, in the same way as do similar components in any other living or inanimate system. But living man responds to his environment. I have intentionally differentiated between reaction and response to emphasize that human adaptation can seldom be regarded as merely the result of man's body reacting with environmental forces. In fact, man's responses are not even necessarily aimed at coping with the environment. They often correspond to an expressive behavior and involve the use of the environment for self-actualization. Health in the case of human beings is more than a state in which the organism has become physically suited to the surrounding physiochemical conditions through passive mechanisms; it demands that the personality be able to express itself creatively.

> Human life is thus the outcome of the interplay between three separate classes of determinants, namely: the lasting and universal characteristics of man's nature, which are inscribed in his flesh and bone; the ephemeral conditions which man encounters at a given moment; and last but not least, man's ability to choose between alternatives and to decide upon a course of action. Ideally, the goal of medicine has always been to help man function successfully in his environment--whether he is hunting the mammoth, toiling for his daily bread, or attempting to reach the moon.

In many respects, Dubos is asking people not only to think about, but to consider that which many regard as unthinkable. People are not passive objects of their environment, but are active creators of their life circumstances. When their health has deteriorated and their life has been threatened, they do what comes most naturally--adapt. Thus, to those who seek to take away or discount this element of the human condition, the response from those most deeply insulted is uniform--are the thieves truly human?

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CHAPTER 27

OVERVIEW OF THE COST ANALYSES

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A. INTRODUCTION

This chapter provides an overview of the methods used to estimate the costs of heart transplantation in the National Heart Transplantation Study (NHTS) and a summary of the salient findings from the following three chapters, which describe the cost analyses in detail. The overall objective of the cost analyses is to project the costs to HCFA were Medicare to cover heart transplantation.

This objective, however, is more broad than it sounds. First, the projection requires information from all other components of the study: need, survival, organ procurement, psychosocial, legal, and ethical. Need and procurement will affect the number of transplants performed. Survival has obvious direct affects on costs. Psychosocial factors are important in determining the cost-effectiveness of the technology. Legal and ethical considerations may affect costs by affecting the number and types of institutions that provide heart transplantation or the characteristics of individuals who receive transplants. Second, HCFA must look beyond costs to the federal government alone both because their coverage decision will set a precedent for other insurance programs, public and private, and because the government would be allocating scarce societal resources and not simply scarce government resources. Therefore, a comparison of the cost-effectiveness of this technology with alternatives, from society's point of view, is important.

Meeting this objective requires the completion in sequence of three major tasks:

- Estimating the historical costs of heart transplantation using data from existing heart transplant centers.
- Estimating the cost-effectiveness of heart transplantation (in terms of cost per life year gained) and comparing it with alternatives.
- Projecting aggregate costs to HCFA for five years after a coverage decision and subjecting the projection to a sensitivity analysis.

Each of these three major tasks is treated in detail in a separate chapter. In the next section, methods used for each task are described at a general level. The third section presents the key empirical results from the three chapters, and the final section summarizes the major findings and limitations.

B. OVERVIEW OF COST ESTIMATING METHODS

These three chapters focus on what can be called the "direct medical costs" of transplantation, in the terminology of Hodgson and Meiners (1982). Following their use, other costs include: (1) direct nonmedical costs--other costs borne by patients to obtain care, such as transportation costs and temporary lodging expenses; (2) indirect costs--the value of output lost because of illness; and (3) psychosocial costs--effects on the quality of life of patients. These three other types of costs are also addressed in the NHTS, but in other chapters of the report.

1. COLLECTION OF HISTORICAL COST DATA

As described in the chapters on data collection and methodology, the six transplant centers participating in the study

were asked to provide medical cost information for all their patients during the period January 1, 1978 to June 30, 1983. The information was to cover not only living and deceased recipients but also all candidates and all persons undergoing evaluation for candidacy. Patients who were evaluated, declared candidates, or transplanted prior to this period are included in the study if they had expenses at one of the transplant centers during this period. But only their hospital utilization during this period is analyzed.

For these cost analyses, the transplantation experience is broken into three major phases: (1) the pre-transplant phase, including evaluation and candidacy; (2) the transplant phase, from operation to initial discharge or death; and (3) the post-discharge phase, including all the years since initial discharge. The basic objective of the historical cost analyses is to describe the average medical costs per patient in each of these phases.

The description, however, takes account of a number of complications. First, there is the issue of what is meant by "cost." Conceptually, an estimate of the true opportunity costs of the resources used is desirable. Ideally, in well-functioning competitive markets this could be measured by the market prices of the resources used. In the U.S. hospital industry, the charges, which are effectively list prices for various hospital services, are unlikely to be a reliable guide to the opportunity costs of the resources (Finkler, 1982). Previous analyses of heart transplant costs have relied on reported hospital charges. This study, which is aimed at projecting costs to Medicare, goes one step further by adjusting these

charges to "costs," as interpreted in Medicare's hospital cost-reimbursement system. (This system was recently supplanted by a prospective pricing system, but this change does not alter the study design, though it will affect the implications.) How these Medicare "costs" are related to true opportunity costs is unknown, but is discussed in a qualitative fashion in one of the detailed chapters. As described in detail in Chapter 28, hospital costs to Medicare are estimated by multiplying reported charges by the relevant cost-to-charge ratios and per diem costs found in each center's annual Medicare Cost Report. Further, estimates from various years are converted to constant 1983 dollars, through multiplication by a price index.

A second complication for the description of costs is the difficulty of gathering cost information outside the transplant center billing records. Table 27-1 summarizes the sources for the cost data. The bulk of the data, as well as the bulk of costs, are related to hospitalization at the transplant center. This information was directly abstracted from hospital records. In general, charges for physician services do not appear in these billing records. The study relied instead on a short, supplementary questionnaire sent to the centers to gather information on usual physician fees. Data on post-transplant costs at hospitals other than the transplant center, and from other physicians, and for outpatient immunosuppressive drugs were obtained directly from the patients.

These various data are used to calculate average cost by cost category (physician, hospital, or drugs) and by treatment phase (pre-

Table 27-1
Source of Medical Cost Data by Period and Type of Service

PERIOD	TYPE OF SERVICE: TRANSPLANT CENTER HOSPITAL COSTS	TRANSPLANT CENTER PHYSICIAN SERVICES COSTS	COSTS AT OTHER HOSPITALS	COSTS FOR OTHER PHYSICIAN SERVICES
I. PRETRANSPLANT				
A. Evaluation	1, 2	1, 2, 3	*	*
B. Candidacy	1, 2	1, 2, 3	4	**
II. TRANSPLANT	1	2, 3	*	*
III. POST-DISCHARGE	1	3	4	4

Key to Sources:

1. Recipient Hospital Records Abstraction
2. Nonrecipient Hospital Records Abstraction
3. Physician Questionnaire
4. Patient Questionnaire

*Not Applicable
**Ignored because small.

and post-transplant). Where feasible, finer distinctions are made within cost category (e.g., among types of hospital costs or types of physicians). A description of source of payment historically is provided in an earlier chapter. Ultimately, it would be desirable to subject average cost by phase and category to a simple statistical analysis to relate them to patient characteristics, such as age and sex.

2. ESTIMATING THE COST-EFFECTIVENESS OF HEART TRANSPLANTATION

Using the average cost estimates provided in Chapter 28 and survival probabilities, it is a conceptually straightforward exercise to calculate the cost-effectiveness of heart transplantation. Weinstein and Stason (1977) have described well the basic methodology. The goal is to calculate the ratio of net medical care costs to net effectiveness. The numerator reflects all additional costs incurred because the patient receives a heart transplant. These are net costs, because the costs that would have been incurred without the transplant are subtracted from the cost of the transplant. The denominator reflects both the change in life expectancy as a result of the transplant and the change in quality of life. Again, this is a net concept because only life expectancy and quality of life above what would have occurred in the absence of a transplant are counted. The final ratio is typically expressed in present value terms as either cost per life year gained or cost per quality-adjusted life year gained. This study focuses on the former.

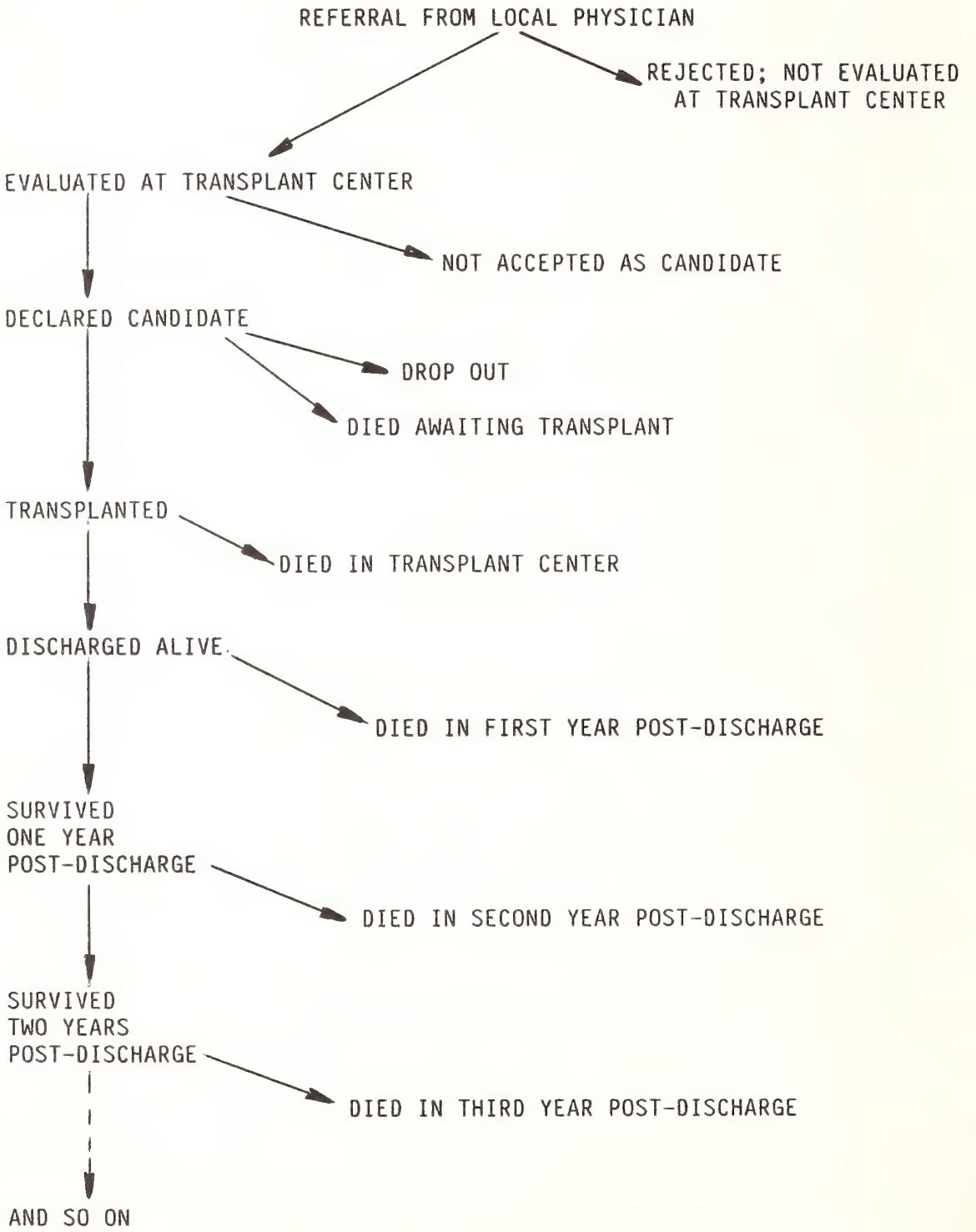
The preceding definition suggests the major practical difficulty in estimating this ratio. Both costs and survival that

would have been incurred in the absence of a transplant are unobservable. They are only observable for those candidates who did not receive a transplant. As discussed in Chapter 29, this leads to a number of potential selection biases. This flaw is unavoidable in nonexperimental data; however, several steps are taken to minimize its impact. Primarily, the results are subjected to a sensitivity analysis based on alternative assumptions about expected costs and survival without transplantation. The alternative assumptions are derived from estimates using the data on candidates during the period prior to transplantation.

Figure 27-1 shows descriptively the events involved in the heart transplantation process. It is important to recognize that the costs of providing a heart transplant to a patient do not just begin on the day of the transplant. There are net costs associated with the pre-transplant period. These include the costs of the evaluation at the transplant center to the extent that these would not have occurred otherwise. Additional resources may be spent to keep a candidate alive (because a person is a candidate). Furthermore, these costs must be inflated because several patients must be evaluated and several candidates declared for each patient who eventually becomes a recipient.

The costs incurred after the transplant are more obvious. Each of the events in Figure 27-1 has both a probability of occurring and an associated cost. These are multiplied to compute expected costs. Survival itself (measuring effectiveness in the denominator) can be thought of as a similar probability tree. Both expected costs

Figure 27-1
FLOW DIAGRAM OF HEART TRANSPLANTATION
SELECTION AND SURVIVAL

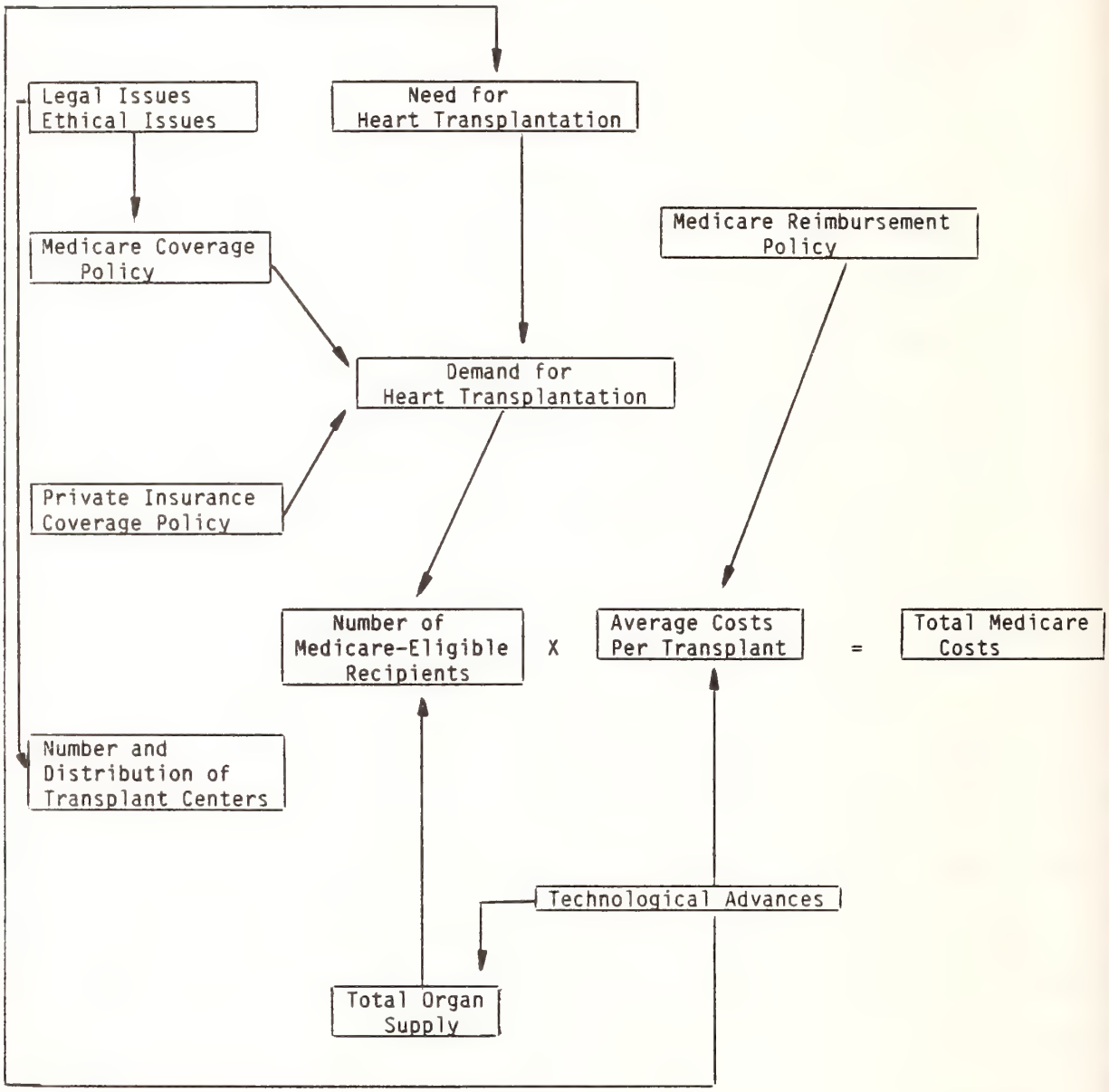


and expected survival are discounted into a present value using several different discount rates. The final step in the calculation is to subtract discounted expected costs and discounted expected survival without the transplant from these quantities, and then to compute the ratio.

3. FIVE-YEAR PROJECTIONS OF COSTS TO MEDICARE

Projection for five years of the costs of Medicare requires not only the estimates of medical costs from Chapters 28 and 29, but also information on need and organ supply and from the legal and ethical components of the study. Figure 27-2 illustrates how the several components of the study are involved, though not exhausting all of the possible interconnections. The number of transplants performed in a year depends on the total number of donor hearts available and the share that go to Medicare-eligible recipients. The effective demand by Medicare-eligible potential candidates is determined by the need among the Medicare-eligible and Medicare coverage provisions (e.g., patient age limitations or provider limitations). Technological advances (such as cyclosporine) can affect all components of the projections, but most notably need, organ supply, and cost per transplant. The number of transplants performed on the Medicare-eligible is multiplied by the expected costs, as estimated in Chapter 28 using Medicare's former cost-reimbursement methodology. In the future, this cost would depend on the reimbursement rate set under the new prospective pricing system.

Figure 27-2
Factors Affecting Medicare Transplant Costs



The key empirical results of these projections and sensitivity analyses are summarized in the next section. Chapter 30 describes in detail the various assumptions used and sensitivity analyses performed.

C. SUMMARY OF RESULTS

1. HISTORICAL COSTS

Table 27-2 shows the final cost parameter estimates derived from the analysis in Chapter 28. The base case estimate represents what is regarded as the most likely or realistic estimate. Each cost estimate is for the costs that would be borne by HCFA and includes the elements identified in Table 27-2, such as hospitalization and physician costs.

The pre-transplant phase includes evaluation and candidacy costs. The marginal cost of the evaluation at the transplant center is estimated to be $3,700. The average costs incurred during the evaluation period are much greater than this, but it is assumed that most of them would have been incurred in any case. The net candidacy cost per month for those eventually transplanted was assumed to be zero, again, on the grounds that the reported costs would have been incurred in any case. The candidacy cost estimate shown, based on the experience of recipients prior to transplant, is a very important parameter. It represents the best estimate of what the monthly expenses would have been without a transplant. A potential fallacy of this extrapolation is the presumption that the recipients would have incurred as much cost had they died at their local hospitals. It

Table 27-2[a]
Summary of Parameter Estimates for
Medical Costs to HCFA

Phase and Element	Base Case	Range Low	Range High
I. PRE-TRANSPLANT			
A. Evaluation Cost	$ 3,700	$2,700	$5,200
B. Candidacy Cost (per month)	$ 6,151	$1,000	--
II. TRANSPLANT PERIOD COSTS			
A. Survivors	$75,085	$60,843	$88,675
B. Decedents	$80,286	$67,230	$98,502
III. POST-DISCHARGE ANNUAL COSTS			
A. First Year:			
- Survivors	$ 9,535	--	$14,016
- Decedents	$11,810	--	$17,684
B. Second Year and Beyond			
- Survivors	$ 6,261	--	$ 7,975
- Decedents	$ 8,911	--	$12,750

[a]This table is identical to Table 28-18.

would be extremely beneficial if a test of this assumption could be undertaken.

The costs during the transplant hospitalization were estimated at $75,085 for survivors and $80,286 for those who died before discharge. These are weighted averages based on 1983 heart transplant volume at the centers. Although the estimates show higher average costs for those who die, this differential should not be regarded as stable. Some centers exhibited the opposite pattern.

The estimates for the years post-discharge are largely based on transplant center records of hospitalization at the transplant center. Because of the difficulty of obtaining costs at other locations, the estimates could well understate the actual costs. As would be expected, the costs associated with dying are often substantial, ranging from $9,000 to $12,000 in the year of death.

2. COST-EFFECTIVENESS

In addition to the cost estimates shown in Table 27-2, the computation of cost-effectiveness requires estimates of the rates and probabilities of the events shown in Figure 27-1. These estimates, shown in Table 27-3, are derived from other components of the NHTS; their derivation is described in detail in Chapter 29.

Table 27-4 presents the results of the cost-effectiveness analysis. The base case estimate is $23,478 per life year gained. Recipients were, on average, projected to have an undiscounted net life expectancy of 6.5 years; discounted (at 6 percent) net life expectancy was 4.1 years. Similarly discounted costs for the base case were $96,237 in present value terms. The cost effectiveness ratios were

Table 27-3[a]
Summary of Rates and Probability
Parameter Estimates

Rate or Probability	Estimates		
	Base Case	Low	High
Number of Medicare patients evaluated per candidate.....	1.5	1.3	4.0
Mean length of candidacy prior to transplant (days).....	35	--	--
Number of Medicare candidates per recipient.....	1.2	1.15	2.0
Mean length of alternative survival post-transplant (months).....	3.0	1.7	9.0
Conditional Survival Probability:			
Transplant period.....	.80	.75	.85
One year.....	.70	.60	.75
Two years.....	.90	.85	.94
Three years.....	.90	.85	.94
Four years.....	.90	.85	.94
Five years.....	.90	.85	.94
Six years.....	.95	.90	.97
Seven years.....	.95	.90	.97
Eight years.....	.95	.90	.97
Nine years.....	.95	.90	.97
Ten years.....	.95	.90	.97
Eleven to nineteen years..	.98	.98	.98
Discount rate (%)	6.0	2.5	10.0

[a]This table is identical to Table 29-2.

Table 27-4[a]
Cost-Effectiveness Results
(Expressed in Cost per Life Year Gained)

I. BASE CASE RESULTS (20-year Time Horizon; Discount Rate = 2.5)

Period	Expected Cost	Survival Probability
0	$76,125	.800
1	8,152	.560
2	3,674	.504
3	3,306	.454
4	2,976	.408
5	2,678	.367
6	2,362	.349
7	2,244	.332
8	2,132	.315
9	2,026	.299
10	1,924	.284

Alternative Cost = $18,453

Cost per Life Year Gained = $23,478 ($96,237/4.099 years)

II. SENSITIVITY RESULTS (Cost per Life Year Gained in 1983 dollars)

	Discount Rate		
Alternative Survival	2.5	6.0	10.0
1.7 months	$21,467	$25,445	$30,258
3.0 months	$19,811	23,478	28,002
9.0 months	$14,152	16,486	19,574

[a]This table is identical to Table 29-5.

subjected to a sensitivity analysis with varying plausible assumptions about discount rates and the costs of alternative treatment (i.e., not receiving a transplant). The resulting ratios fell in the range of $14,000 to $30,000 per life year gained.

By way of comparison in Chapter 29, it is noted that these survival probabilities are not as favorable as the results for kidney dialysis and transplantation, where five-year patient survival is 52% and 59% (for cadaveric transplants), respectively. However, five-year graft survival for cadaveric transplants is only 31%, and both graft rejection and maintenance dialysis costs can be substantial. In fact, when compared specifically with kidney transplantation with regard to cost-effectiveness, heart transplantation does not seem to be clearly more expensive per recipient from HCFA's point of view. But compared with the cost-effectiveness ratios of other medical technologies that have been evaluated, heart transplantation appears to fall at the high end of costs.

3. FIVE-YEAR PROJECTIONS

Table 27-5 shows the projected costs to Medicare over the five-year period 1985-9. Three assumptions are crucial: (1) the projected total volume of heart transplantation, which is mostly a function of organ supply; (2) the proportion of recipients who are Medicare beneficiaries, which depends on the Medicare coverage provisions, and (3) the expected alternative cost, which is based on the limited evidence from candidates awaiting transplant.

The base case, which assumes that current coverage provisions continue, projects the number of total recipients in 1985-9 to be 400,

Table 27-5[a]
Five-Year Projections of the Costs of Heart
Transplantation Coverage to HCFA (in 1983 dollars)

I. PROJECTED NUMBER OF MEDICARE RECIPIENTS

	Base Case (Without Expanded Coverage)	Expanded Coverage	Expanded Coverage and Higher Volume
1985	29	400	1000
1986	32	440	1100
1987	35	484	1210
1988	39	532	1331
1989	42	586	1464

II. PROJECTED COSTS TO HCFA (in millions)

	Base Case (Without Expanded Coverage	Expanded Coverage	Expanded Coverage and Higher Volume
1985	2.0	$27.4	$68.4
1986	2.4	38.5	81.2
1987	2.7	37.1	92.8
1988	3.1	42.0	105.2
1989	3.4	47.4	118.5

III. PROJECTED SURVIVORS (end of year)

	Base Case (Without Expanded Coverage)	Expanded Coverage	Expanded Coverage and Higher Volume
1985	20	272	680
1986	38	519	1,297
1987	56	769	1,922
1988	75	1,024	2,562
1989	93	1,289	3,222

[a]This table is identical to Table 30-5.

440, 484, 532, and 586; Medicare-eligible recipients are then 29, 32, 35, 39, and 42, respectively. An alternative scenario--the expansion of coverage to all recipients--is shown in the second column. The third column assumes both expanded coverage (similar to kidney transplants) and a much larger number of transplants, which assumes that organ supply expands vastly.

It is clear that under the base case assumptions the cost to Medicare of covering heart transplantation would be relatively small--from $2 to 3.5 million (in $1983 dollars) per year in the period 1985-9. Even under the expanded coverage the annual cost remains less than $50 million. And the addition of expanded volume would yield costs in 1989 of about $120 million for some 3200 beneficiaries (alive at the end of the year). This is much less than the approximately $2 billion spent on the ESRD Program. Of course, the ESRD Program serves over 70,000, while this heart transplant group would be only about 1,300 in 1989 under the second scenario. Alternatively, per recipient expense in the ESRD Program is about $30,000 per beneficiary. For a heart transplant program, the estimated cost would average about $37,000 per beneficiary in 1989.

Finally, sensitivity analyses revealed that the projections of aggregate costs to HCFA are not very sensitive to alternative plausible assumptions about costs or survival probabilities. The major issue is how many hearts will be transplanted. Current projections are that the supply available in the U.S. is very small as compared with need.

D. CONCLUSION: MAJOR FINDINGS AND LIMITATIONS

This chapter has provided an overview and summary of the three detailed chapters to follow. Even so, it should be apparent that a long trail of assumptions and more or less educated guesses must be made in the course of this analysis. The rationale for these assumptions is described in the chapters to follow. Numerous caveats and disclaimers are provided in the detailed chapters. An attempt is made to provide enough information so that the reader can experiment with alternative assumptions.

The results here are premised on major findings from other portions of the NHTS. Both the cost-effectiveness analysis and the aggregate cost projections rely on survival probabilities from the survival analyses. And, perhaps most importantly, the aggregate cost projections are based on the finding that the very scarce supply of organs (relative to need) will keep the annual volume of heart transplants at a low level for the foreseeable future.

To summarize, the major findings of the cost-analyses are:

1. Heart transplantation is currently a costly medical procedure, with average first-year net costs (to HCFA) on the order of $80-85,000. Costs in later years are also substantial--on the order of $6-12,000 per year.

2. The average cost-effectiveness ratio for heart transplantation is $20-25,000 per life year gained. This is a high cost relative to many medical technologies, but perhaps favorable when compared with kidney dialysis and transplantation.

3. The projected aggregate costs to HCFA depend crucially on assumptions about coverage and available organ supply. The costs could be as low

as $2-3.4 million per year for period 1985-89, or as high as $70-120 million. In any case, the program will be small compared to the ESRD Program.

This is not the place to reiterate all of the numerous limitations expressed in the chapters which follow. Perhaps highlighting of only four major limitations will serve to induce appropriate caution on the part of readers:

1. The estimated costs are costs to HCFA, and therefore only partial, not total, costs to society. For this reason as well as others, the resource costs to society are probably understated.

2. Estimated cost-effectiveness is average cost-effectiveness; patients with more favorable characteristics could have much lower cost-effectiveness ratios.

3. The crucial estimates of survival and costs without transplantation are very uncertain.

4. The projected aggregate costs are determined largely by the volume of transplants done, but the projected volume is based on an extrapolation from the kidney transplant experience, which is itself a matter of controversy.

Despite these limitations of the analysis, several important results emerge. These findings, as summarized above, are robust, unlikely to be altered by reasonable modifications of the assumptions made here.

The above findings are not, however, meant to pre-judge the question of Medicare coverage. The aim is to provide policymakers with estimates upon which to base a coverage decision. Of course, other facets of the NHTS must bear upon this decision, including legal and ethical considerations as well as the quality of life of recipients.

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CHAPTER 28

THE MEDICAL COSTS OF HEART TRANSPLANTATION

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A. INTRODUCTION

The purpose of this chapter is (1) to describe the methods used in the National Heart Transplantation Study to estimate the medical costs of transplantation, and (2) to present the estimates. These results provide the basis for the estimation of the cost-effectiveness of heart transplantation (in Chapter 29) and for the projection of costs to Medicare over a five-year period (in Chapter 30).

Section B is a background section, summarizing previous reports on the costs of heart transplantation. Section C presents the conceptual framework used to organize the cost estimates. Section D describes the sources of data and the data collection instruments used. Section E presents the results by conceptual category. (Those readers interested primarily in the estimates can skip directly to this section since most of the discussion is self-contained.) Section F concludes the chapter with a brief summary of the medical costs and a discussion of some limitations of the methods and estimates.

B. BACKGROUND: PREVIOUS ESTIMATES OF HEART TRANSPLANT COSTS

A few major centers have reported the "costs" of transplantation at their respective facilities in the literature. What is most striking about these reports is the variability in costs. Copeland et al. (1981) at Arizona report first-year average cost at "about $50,000 per patient," with second-year costs being $22,500 for one patient and $239 for another. Pennock et al. (1982) at Stanford report average hospitalization costs of $100,000 for 97 patients treated over the period 1973-1979. However, more recent experience at Stanford shows a

decline in this to $83,000 for 13 patients treated from May, 1980 to December, 1981 and an even lower figure of $57,000 for the subset of those patients who have successfully been treated with cyclosporine. (Their average length of stay was 45 days as compared with the 65 days of earlier patients.) Stanford reports average total costs for follow-up hospitalizations and outpatient visits to be about $29,000 in the remainder of the first year, $18,000 in the second year, $18,000 in the third year, and $15,000 in the fourth year. Thomas and Lower (1978) at the Medical College of Virginia report the first year costs to be about $25,000 and the costs in following years to be $2,500. Helson (1981) reports the estimated first year costs in Great Britain to be about $44,000.

The variance across sites in these estimates of costs could stem from a number of obvious factors:

- Different definitions of cost.
- Different resources may be included in the accounting at different sites or accounting methods may differ.
- Outcomes from transplantation affect costs and may differ by site.
- Charges for particular items will differ by site.
- Treatment protocols may differ by site.

It is likely that all of these play some part in the reported differences.

Another salient feature of the above estimates is that they focus on the medical costs of the transplant procedure per se and do not consider other aspects of a heart transplantation program. To be

fair, these analyses do not pretend to be comprehensive. Though preliminary, to date the most comprehensive analyses of heart transplant costs have been by Reiss et al. (1982) and Hellinger (1982). The most notable feature of these studies is that they add to Stanford hospitalization cost estimates some first-cut estimates for (1) the costs of procuring the heart (donor costs), (2) professional surgical fees associated with the transplant, (3) pre-transplant evaluation costs, and (4) travel and lodging costs of recipients. All of these are important elements of the costs to society. Other costs, such as second-year cardiologist fees, were not included because they were not available. The data collected here help to fill these gaps.

Further attention at the conceptual level is also warranted since these studies ignored two potentially important factors: (1) the costs of a heart transplantation program associated with those candidates who died before receiving a transplant, i.e., their evaluation costs and costs while awaiting transplant, and (2) the cost that would have been incurred by the potential and eventual recipients had no heart transplantation program existed. Most graphically, if these individuals dying of end-stage cardiac disease would have spent their last few months in an intensive care unit at a local hospital, then the net resource costs to society of their receiving a transplant will be much less than if they had died at home and with little medical attention. Though difficult to measure, a good estimate of this magnitude is essential if the net costs of a heart transplant program to society are to be understood.

In describing the conceptual framework in the next section, the basic approach is to break down real world processes into a series of discrete periods and events having various probabilities of occurring. The estimates of the average cost of an event and of the probability of its occurring are made separately but then combined in Chapter 29 to compute the expected cost. In nearly all cases, the probabilities used in the cost analyses were estimated in the epidemiologic, survival, and organ procurement portions of the NHTS.

C. CONCEPTUAL FRAMEWORK

Although estimating the historical costs of transplantation is more or less a descriptive exercise, the many possible ways of carrying out the task are not equally effective when it comes to understanding, interpreting, and extrapolating from the results. The conceptual framework used here reflects a series of choices about the method of presentation. Two major choices deserve comment at the outset.

First, since the purpose of the study is to project costs to Medicare, HCFA's cost-reimbursement methods are used in estimating costs. That is, individual patients' hospital charges are transformed by Medicare cost-to-charges ratios and per diem rates to produce costs (see Appendix 28-A). The extent to which the resulting estimates approximate resource costs to society is an open question.

Second, since the focus of the study is on costs to HCFA, not resource costs to society, the estimation approach must consider only the Medicare population at risk. The costs to HCFA depend both on

coverage decisions (who is eligible) as well as reimbursement methods (how HCFA's, as opposed to the patient's share, is defined).

This focus on HCFA's costs is important to remember. Basically, the question is: if Medicare were to extend coverage to heart transplantation, what would be the net increment to HCFA's costs in future years. In general, this will not correspond to the marginal costs to society, though it may approximate the bulk of them. For example, suppose that all U.S. citizens with end-stage cardiac disease, as determined medically, became immediately eligible for Medicare. Such a provision, similar to the ESRD coverage provision, would have very different implications than a provision which covered only those eligible for Medicare under current rules.

In tracing through the descriptive model, it is useful to keep in mind what is defined as the "base case." The base case reflects what is assumed to be the most likely or most realistic estimate. But the number of assumptions are many, and all are not held with the same degree of confidence. In order to test the sensitivity of the results to alternative assumptions, sets of "lower bound" and "upper bound" estimates are specified. The lower bound cost assumptions are those which lower the net cost of transplantation. For example, lower transplant costs and higher alternative treatment costs lower net costs. The upper bound cost assumptions are those which are likely to increase total costs.

A major base case assumption is that coverage is extended only to those who would be Medicare eligible under current provisions. Because the current medical criteria generally use age 55 as a cutoff,

the Medicare-eligible are those eligible via long-term disability. Alternative coverage provisions would suggest some other way of looking at costs. In this report these alternatives and their implications are considered primarily in Chapter 30. More specifically, therefore, the following question is being addressed: what would be the net costs to HCFA were Medicare to cover heart transplantation under current eligibility provisions? The answer requires that an examination of what services would be provided over and above what is currently being done for these Medicare beneficiaries.

The transplant experience can be conveniently broken into three major phases: (1) the pre-transplant phase, (2) the transplant phase, and (3) the post-discharge phase. Table 28-1 lays out cost elements of these phases. The pre-transplant phase involves evaluation for suitability as a candidate as well as candidacy itself--the period of time while awaiting a transplant. The transplant phase is defined to begin on the day of transplant and extends to either discharge from the hospital or death in the hospital. The post-discharge phase applies to those who survive to be discharged and covers the period of time following discharge, often lasting many years.

In estimating costs, it is important to recognize that not all costs are associated with those who receive a transplant. Costs are incurred for those only being evaluated or for those awaiting transplant who die before receiving one. Exactly how these are to be counted depends on the actual Medicare coverage provisions. Again,

Table 28-1
Conceptual Phases: Medical Costs of Transplantation

I. Pre-Transplant Phase

- Costs of initial evaluation for candidacy
- Costs while awaiting transplant

II. Transplant Phase

- Costs during hospital stay following cardiac transplant procedure

III. Post-Discharge Phase

- Costs in years following discharge after transplantation

for this chapter the base case assumption is used to describe the elements of cost.

Consider what this assumption implies for the elements shown in Table 28-1. In the pre-transplant phase, only those evaluation costs over and above what would have been incurred for the Medicare-eligible patient in any case are counted as costs to HCFA. Additional candidacy costs, or costs while awaiting transplant, are those costs over and above what would have been spent to keep the Medicare-eligible patient alive in any case. Similarly, transplant phase and post-discharge phase costs represent net costs to HCFA only to the extent they are over and above what would have been done for these patients otherwise.

D. DATA SOURCES

To estimate the medical costs of heart transplantation, the NHTS relied on several surveys and instruments. The objective was to identify all types of medically related charges made to patients either being considered for a heart transplant or receiving one. Obviously, such charges can arise from a variety of providers for a multitude of different services.

Three particular complicating factors deserve mention. First is the problem of hospital expenses incurred at hospitals other than the transplant center. Such expenses are nearly impossible to obtain retrospectively. They may be approximated, at best, relying on patient recall of the recent past. Second, information on physician charges is not readily available. Such charges are generally not on hospital bills and cannot be gathered centrally. And, third, charges

are not the costs to Medicare. In the recent past (before prospective payment) Medicare reimbursed on the basis of the costs estimated to have been incurred by Medicaid patients. Each of these complications necessitated special efforts to obtain an estimate. The solutions are, however, not perfect and serve to compound the error that already surrounds statistical estimates.

Because of its importance, the most detailed attention was paid to the costs associated with patient hospitalization for the transplant itself. This information was gathered via abstraction from hospital billing records, as part of the transplant recipient medical and hospital records abstraction (as described in Chapter 6).

Table 28-2 summarizes the sources for the data on medical costs. The majority of the effort went into collecting data from the transplant centers, where the bulk of the costs are incurred. Sources 1 and 2 represent direct abstraction from summary sheets on hospital bills. Since hospital bills do not include most charges for physician services, a supplementary questionnaire was sent to each of the six transplant centers (Appendix 28-B is a copy of this questionnaire.) This is Source 3 in Table 28-2. The other major source of information was a survey of 152 living recipients, described in Chapter 5. This, Source 4 in the figure, was chosen as a cost-effective means of gathering data for hospitalization post-transplant at other centers and for other outpatient use. The potential selection bias of estimates from this group was recognized, but has not been adjusted for in the estimates as yet. (Of course, bias should not be a problem for questions about routine costs.)

Table 28-2
Source of Medical Cost Data by Period and Type of Service

PERIOD	TYPE OF SERVICE			
	TRANSPLANT CENTER HOSPITAL COSTS	TRANSPLANT CENTER PHYSICIAN SERVICE COSTS	COSTS AT OTHER HOSPITALS	COSTS FOR OTHER PHYSICIAN SERVICES
I. PRE-TRANSPLANT				
A. Evaluation	1, 2	1, 2, 3	*	*
B. Candidacy	1, 2	1, 2, 3	4	**
II. TRANSPLANT	1	2, 3	*	*
III. POST-DISCHARGE	1	3	4	4

Key to Sources:

1. Recipient Hospital Records Abstraction
2. Nonrecipient Hospital Records Abstraction
3. Physician Questionnaire
4. Patient Questionnaire

* Not applicable
** Ignored because small

Table 28-3 shows the universe of 418 recipients from the six centers included in the study. (Those re-transplanted are excluded from the cost analyses.) Only for those transplanted after 1978 were data collected on hospital charges. However, the post-discharge hospitalization experience (in days, not dollars) was available for many of those transplanted before 1978.

Although the results section presents the data by center, the estimates used in the base case are weighted means of the estimates from all six centers. The weights are based on the volume of procedures in 1983, as reported in Chapter 3. This has some obvious limitations since the future will undoubtedly be different than even the recent past. But using the historical mean would give Stanford an undue weight since they are unlikely to expand their program significantly in the future. Some attempt is made to offset these limitations by doing sensitivity analyses with other values.

E. RESULTS

In this section, estimates of the medical costs related to heart transplantation are presented by phase of treatment. An attempt was made to make the tables as self-explanatory as possible, so that the reader can quickly grasp their meaning by leafing through the tables. In several instances, means are reported by center and then weighted to a grand mean. There is virtually no analysis of intercenter differences in costs or charges. Instead, the objective is to provide the background data for generating the estimates used in subsequent calculations. Readers should be careful to not draw unwarranted prima

Table 28-3
The Distribution of Study Patients by
Year of Transplant and Center

	CALENDAR YEAR							
CENTER	Before 1978	1978	1979	1980	1981	1982[a]	1983	Total
Arizona	0	0	4	5	7	14	9	39
Columbia	3	6	0	4	1	7	7	28
MCV	2	7	5	7	5	6	5	37
Minnesota	0	3	0	2	3	6	6	20
Pittsburgh	0	0	0	3	14	19	13	49
Stanford	119	23	19	20	22	26	16	245
Total	124	39	28	41	52	78	56	418

[a]Not a full year's volume

facie conclusions on these differences. Small numbers of cases, outliers, and the lack of case mix adjustment are factors militating against inferences based on simple comparisons of means. Also, for most parameters, low and high estimates are presented in addition to the base case. They are intended to give an impression of the uncertainty surrounding the base case estimate.

1. PRE-TRANSPLANT PHASE

The pre-transplant period consists of two periods which were defined on the medical records abstraction form as follows:

- Evaluation Period - The evaluation period is the period between the date on which heart transplant evaluation tests were performed on the patient and the date the patient was accepted or rejected as a heart transplant candidate.

- Candidacy Period - The candidacy period is the period between the date the patient was accepted as a heart transplant candidate and the date of the day before the patient received his/her heart transplant. If the patient died prior to receiving a heart transplant, the candidacy period is the period between the date the patient was accepted as a heart transplant candidate and the date of their death.

Basically, each of the six transplant centers was asked to sum all hospitalization costs in each of these two periods. The applicability of these totals depends on what is desired conceptually. For example, suppose that all the costs borne in the period before transplant would have been incurred in any case, even if at another hospital. Then, the additional cost to HCFA is zero.

This assumption is false, strictly speaking, since special studies are required at the transplant centers during the evaluation

period. On the other hand, the additional cost of these studies may be small compared to the total cost of the pre-transplant phase.

a. Evaluation Costs. Table 28-4 shows the mean charges incurred during the evaluation period for recipients at the six centers. Mean days spent in the transplant hospital as well as the mean length of this period are also shown. Mean charges appear to vary considerably across the centers, ranging from $4,500 to $12,000. However, standard deviations are also high. Although the charge categories at the centers are not strictly comparable, the figures show that the bulk of charges are associated with diagnostic tests (such as EKG and cardiac catheterization), lab tests, and room and board. Differences in room and board charges account for a large portion of the overall differences. Mean stay is 8.9 days, and mean length of evaluation period is 11.4 days.

The professional fees charged to inpatients, as shown in Table 28-4, probably vary mostly because of differences in billing practices. In some cases, for example, the hospitals may bill for particular services, in others the physician will bill. Since the professional fees charged across the centers were clearly not comparable, they were assumed to be $200 to cover inpatient charges by pathologists and radiologists. The overall mean charge of $8,339 reflects this adjustment as well as the weighting by 1983 transplant volume. Note that the weighted mean length of stay was 8.9 days.

It is apparent from these figures that the length of the evaluation period is much longer than one might expect a priori. According to the Stanford experience (Oyer et al., 1981): "Evaluation

Table 28-4
Mean Charges, Length-of-Stay and Evaluation Period for Recipients, by Center[a]

CHARGE CATEGORY	CENTER						
	ARIZONA	COLUMBIA	MCV	MINNESOTA	PITTSBURGH	STANFORD	ALL[b]
SUPPLIES	$ 73	6	137	496	71	655	--
OR & ANESTHESIA	1	0	51	588	30	169	--
PHARMACY	148	249	545	935	421	750	--
THERAPY	205	75	95	153	125	194	--
APPLIANCES	8	0	0	0	11	0	--
DIAGNOSTIC TESTS	811	1,572	949	1,270	1,394	1,846	--
BLOOD ADM.	0	96	243	57	142	368	--
OXYGEN & GAS	0	30	104	131	24	0	--
LAB TESTS	794	1,238	732	2,544	1,640	2,244	--
OTHER & MISC.	12	163	1	27	16	51	--
PROF. FEES	880	1,727	753	204	103	240	--
ROOM AND BOARD	1,810	3,642	2,214	5,693	2,708	5,269	
TOTAL	$4,529	8,886	5,763	12,097	6,684	11,105	8,339
(Std. Dev.)	(5,010)	(5,583)	(4,029)	(8,225)	(7,146)	(21,466)	--
HOSPITAL DAYS							
ICU or CCU	4.4	2.8	1.1	4.3	1.6	3.8	--
General Ward	3.3	10.3	7.1	7.9	4.2	4.2	--
Total	7.7	13.1	9.2	12.2	5.7	8.1	8.9
LENGTH OF EVALUATION PERIOD							
Mean	8.5	13.7	12.1	11.5	12.6	9.5	10.8
(Std. Dev.)	(11.5)	(25.0)	(28.8)	(10.8)	(36.4)	(20.8)	--
Mode	3.0	4.0	4.0	4.0	4.0	4.0	4.0
Median	4.4	6.0	6.0	9.2	4.8	4.3	--
NO. OF OBSERVATIONS	23	18	29	19	47	93	229

[a]All charge estimates are in 1983 dollars. Number of observations is for total charge data only.

[b]These are weighted means based on 1983 heart transplant volume, as reported in Chapter 3. For this weighted mean only it is also assumed that each center had professional fees of $200 on the hospital bill. As described in the text, the direct charges by cardiologists for a catheterization was assumed to average $750.

of potential recipients consists principally of a standard history and physical examination, cardiac catheterization, left ventriculography, and coronary angiography. In addition, careful psychosocial assessment is considered important..." (p. 199). Clearly, these procedures do not take 8 to 14 days to perform, as the average might suggest though they do usually entail hospitalization. Indeed, the modal value is 4.0 days.

This difference between the mean and mode suggests that for many patients the care being received in the evaluation period is life-sustaining care that would have been delivered in any case. To get at the conceptually appropriate marginal cost to HCFA of the evaluation, these maintenance costs must be subtracted. Estimating the marginal cost of an evaluation to HCFA is not as straightforward as one might first imagine. It is tempting to merely find out the costs of the procedures done during evaluation, sum them, and add an additional cost for being hospitalized for 4 days. The problem is that for some patients the costs of being hospitalized would have been incurred in any case.

An empirical solution to this problem is the following. The results are summarized in Table 28-5. Each observation of the charges during the evaluation was converted to constant dollar costs, using the cost-to-charges ratios in Appendix 28-A and an inflation adjustment to 1983 dollars based on the medical care component of the Consumer Price Index. (Note that at this stage the estimates rely on recipients alone; at some point the data on nonrecipients who were evaluated should be included.) It was assumed that diagnostic and

TABLE 28-5
The Derivation of Evaluation Costs

I. BASE CASE ESTIMATES[a]

CATEGORY	CENTER						
	ARIZONA	COLUMBIA	MCV	MINNESOTA	PITTSBURGH	STANFORD	ALL
DIAG. & LAB	$1,325	3,283	1,274	2,650	1,913	2,997	--
PROF. FEES	808	808	808	808	808	808	--
ROOM AND BOARD	426	660	408	388	369	508	--
TOTAL	2,559	4,751	2,490	3,846	3,090	4,313	$3,700

II. ASSUMED ALTERNATIVE ESTIMATES:[b]

Lower Bound: $2,700
Upper Bound: $5,200

[a]Diagnostic, laboratory costs use expected charges multiplied by cost-to-charges ratios. Professional charges are assumed to total $1,010 ($750 for catheterization, $200 for other hospital-based physicians, and $60 for cardiologist visits). Room and board costs equal two days multiplied by the per diem cost of semi-private room.

[b]The upper bound estimate assumes only diagnostic, laboratory, and professional fees are relevant and assumes a lower cost for catheterization. The lower bound estimate adds other hospital costs and assumes a four day mean stay.

laboratory costs are fixed costs, which are borne regardless of length of stay. In addition, it was assumed that the mean stay was 2.0 days on the grounds that 50 percent of those evaluated would have a four-day stay and 50 percent would have been hospitalized anyway. This is a rough approximation based on the similarity between the median and mode. This yields a mean evaluation cost of $3,700. An upper bound of $5,200 represents the costs predicted with a 4-day stay, and the lower bound of $2,700 assumes zero net stay and lower professional fees. Note that a more refined analysis could be done to see how total evaluation costs vary by whether the patient is declared a candidate or not, and how this depends on other patient characteristics.

b. Candidacy Costs. The importance of candidacy costs in this analysis cannot be over-emphasized. They are important not because they necessarily represent a large cost associated with heart transplantation, but because, almost the opposite, they are assumed to be indicative of the costs that would have been borne in the absence of a heart transplant program. The higher they are, the lower the net costs of transplantation to HCFA. The candidacy costs are expressed on a per month basis and are combined with an estimate of expected survival without a heart transplant to yield these alternative costs. This multiplication is described in the next chapter. The discussion here focuses on the cost per month.

Use of the candidacy cost data in this way is, admittedly, an imperfect way of dealing with the unobservability of what would happen to these candidates in the absence of a heart transplant program.

This approach assumes zero marginal cost to HCFA during candidacy prior to transplant, which lowers the total cost to the Medicare program. However, there are implicit cost savings post-transplant due to the costs avoided by performing the transplant.

Table 28-6 shows the mean charge data pertaining to the candidacy period collected via medical record abstraction from the six transplant centers. Also shown are the length of the candidacy period as well as the number of days hospitalized at the transplant center during this period. The mean length of candidacy was about 35 days, of which 5.8 were spent in the hospital. These charge data were multiplied by Medicare cost-to-charges ratios for each candidate to obtain the mean hospital cost per patient at each of the six transplant centers. This mean cost estimate by center was then divided by the number of months of candidacy to produce mean hospital costs per month. These costs are shown at the bottom of Table 28-6.

The overall mean cost for transplant center treatment is $4,287 per month, but the great variability in costs and charges across centers is troubling. For example, Arizona has by far the longest mean candidacy period and the lowest total expenses per candidate. Two factors play a part in this: (1) the small number of observations, with one outlier with a candidacy of over 3 years; and (2) some Arizona recipients may be housed at a nearby veterans hospital during candidacy. As described below, the attempt to correct for this latter factor is also problematic. At best, these estimates must be recognized as very imprecise.

TABLE 28-6
Candidacy Period: Mean Charges, Hospital Days, Length of Period, and Costs per Month by Recipients, by Center[a]

	CENTER						
CARGE CATEGORY	ARIZONA	COLUMBIA	MCV	MINNESOTA	PITTSBURGH	STANFORD	ALL[b]
SUPPLIES	$ 3	0	306	108	296	392	--
OR & ANESTHESIA	11	31	34	25	141	148	--
PHARMACY	12	338	959	212	561	452	--
THERAPY	5	46	124	12	117	89	--
APPLIANCES	1	0	6	0	24	1	--
DIAGNOSTIC TESTS	72	688	469	81	306	314	--
BLOOD ADM.	0	156	322	14	231	113	--
OXYGEN & GAS	0	50	147	14	0	0	--
LAB TESTS	36	555	823	543	916	965	--
OTHER & MISC.	0	8	1	35	3	14	--
PROF. FEES	36	572	290	31	80	86	--
ROOM AND BOARD	18	3,279	3,295	1,857	2,369	1,906	--
TOTAL	879	5,724	6,805	2,935	5,042	4,043	$4,682
(Std. Dev.)	(2,360)	(6,336)	(8,066)	(6,044)	(8,020)	(9,180)	
HOSPITAL DAYS							
ICU or CCU	0	3.5	2.5	.2	2.3	1.0	--
General Ward	.7	7.3	9.7	1.9	2.8	1.5	--
Total	.7	10.8	12.2	2.1	5.0	2.6	5.8
LENGTH OF CANDIDACY PERIOD							
Mean	89.7	29.5	16.6	31.1	25.2	40.9	35.0
(Std. Dev.)	(194.2)	(26.0)	(17.8)	(36.3)	(36.1)	(49.3)	--
Median	33.5	21.5	10.0	20.0	7.3	26.3	--
COSTS PER MONTH							
Center	$141	$4,272[c]	$11,561	$3,363	$4,037	$2,149	4,287
Other Hospitals	--	--	--	--	--	--	1,864
All	--	--	--	--	--	--	6,151
NO. OF OBSERVATIONS	35	23	32	19	49	89	247

[a]All charge estimates are in 1983 dollars. Number of observations applies only to charge data. This is the reason, for example, that the subtotals for Arizona do not approximate the total.

[b]This is the weighted mean based on 1983 heart transplant volume, as reported in Chapter 3. For the weighted mean, it is assumed that physician fees billed by each center average $75--to cover radiologist and pathologist charges. As explained in the text, fees for management of patient by cardiologist or other physician are assumed to be $30 per day.

[c]Based on charges, since costs exceeded charges.

It is difficult to obtain an estimate of all medical costs incurred during this period because data on physician services used by each patient are not available and hospital care at other facilities is difficult to obtain. Physician costs per day of hospitalization are assumed to be $24 per day (.80 x $30). Also, living recipients were asked their total expenses during this period at other hospitals. On average, these expenses came to $3,300 during candidacy. Applying the overall national average cost-to-charges ratio of 65 percent (HCFA, 1984) yields costs of $2,145, and adjusting to one month implies costs of $1,864. Assuming an average candidacy of 35 days, when summed, these three figures imply a total cost per month of candidacy of $6,151. This is the figure used below in the cost-effectiveness analysis and in the projections.

The figure of $6,151 per month is certainly substantial. It raises the question of whether extra effort is going into keeping these candidates alive, versus what would have occurred otherwise. Consider some other sources of indirect evidence.

First, Lubitz and Prihoda (1984) found that medical expenses associated with the deaths of Medicare enrollees over age 67 in 1978 accounted for 28 percent of Medicare expenditures, yet the decedents were only 5.9 percent of enrollees. Their mean expense of $5,801 in the last year of life for decedents age 67-69 was about 10 times that of survivors. Interestingly, however, "only 6 percent of persons who died had more than $15,000 in Medicare expenses in their last year of life" (p. 117). Heroic efforts to extend life may not be as prevalent

as is commonly believed. Inflating these figures to 1983 dollars implies annual costs of $9,444 for decedents age 67-69.

Second, evidence from the post-transplant deaths of recipients is presented below. The figures suggest that expenses at transplant hospitals for recipients who died in their first year post-discharge average $10,401. (Remember, this may represent a mean survival of one-half year post-discharge.) This is far below the $74,000 per annum that would be implied by the above estimate.

Third, evidence from the ESRD Program (Eggers, 1983) which is discussed in the next chapter shows very substantial annual costs--on the order of $30,000-$60,000 (in 1979 dollars)--for ESRD patients who die. The problem is that these figures reflect, to an unknown degree, the high costs of dialysis and the high costs of the transplant procedure. But the difference in costs between those kidney transplant recipients who survive the first year with a functioning graft ($32,067) and those who die in the first year ($62,886) suggests a cost of dying as high as $30,000.

All of these sources suggest that the costs of dying are usually substantial. This analysis cannot overlook them. On the other hand, the assumption that $6,151 per month would be applied indefinitely is probably too strong. The costs in the last year of life are probably not uniform by month over that period, but instead occur most heavily at the very end. This suggests that the cost of $6,151 per month is likely to become a worse assumption the longer alternative survival is postulated to be. For these reasons, no upper bound estimate is presented. The lower bound is set at $1,000 per

month. This issue is addressed further in the next chapter on cost-effectiveness analysis.

2. TRANSPLANT PHASE COSTS

The transplantation period is the time between the day the patient received a transplant and the day of discharge (either alive or dead). The major costs incurred during this period are inpatient costs related to hospitalization. Costs for physician services utilized during this period and costs for organ procurement are discussed separately.

a. Costs of Inpatient Hospitalization. As described above and in Chapter 6, data from hospital billing records were abstracted for all patients transplanted at the six centers between January 1, 1978, and June 30, 1983. This yielded data on some 274 patients of whom 208 were discharged alive and 66 were discharged dead.

Tables 28-7 and 28-8 summarize the charge and length of stay data gathered for these patients by center. The first table presents the results for those who were discharged alive, and the second table for those who were discharged dead. All data have been converted to 1983 constant dollars. Note that because of accounting differences across centers, comparisons across centers within the charge cost categories shown are inappropriate. (Note also that organ procurement costs are excluded from these estimates.) The mean charge for a surviving recipient was $71,521 with a mean length of stay of 55.9 days. Those who died had an average charge of $81,348, and an average length of stay of 38.3 days, representing a combination of patients who died within a few days of the operation and a small subset of

Table 28-7
Mean Charges and Days for Transplant Hospitalization
for Those Discharged Alive, by Center[a]

CHARGE CATEGORY	CENTER						
	ARIZONA	COLUMBIA	MCV	MINNESOTA	PITTSBURGH	STANFORD	ALL[b]
SUPPLIES	$ 6,580	221	4,088	3,762	2,386	6,144	--
OR & ANESTHESIA	2,456	6,833	4,301	4,290	16,485	7,918	--
PHARMACY	6,371	4,427	11,922	7,807	4,024	6,017	--
THERAPY	2,176	1,685	2,035	883	1,610	1,201	--
APPLIANCES	953	143	-0-	-0-	115	24	--
DIAGNOSTIC TESTS	5,404	16,588	4,128	8,316	7,899	4,896	--
BLOOD ADM.	1,106	3,688	1,972	2,282	4,107	864	--
OXYGEN & GAS	-0-	164	446	652	-0-	-0-	--
LAB TESTS	10,979	10,616	10,002	10,491	11,826	21,819	--
OTHER & MISC.	135	337	8	18	35	28	--
PROF. FEES	13,168	32,167	2,332	1,030	952	1,615	--
ROOM AND BOARD	14,468	26,834	20,774	15,729	18,282	39,286	--
TOTAL	$63,797	103,702	63,087	55,258	67,722	89,346	--
(Std. Dev.)	(25,029)	(48,096)	(23,422)	(26,642)	(22,710)	(39,400)	
ADJUSTED TOTAL	$51,879	72,785	62,005	55,478	68,020	89,981	$71,521
HOSPITAL DAYS							
ICU or CCU	31.3	23.3	11.5	27.9	6.3	30.9	--
General Ward	25.1	40.7	66.4	8.0	45.5	19.8	--
Total	56.4	64.0	77.9	35.9	51.8	50.7	55.9
NO. OF OBSERVATIONS	31	12	17	12	37	99	208

[a]All charge estimates are in 1983 dollars. Histocompatibility lab charges and heart acquisition costs are not included. Number of observations applies to mean total charges. Other lines may differ because of missing values.

[b]This is the weighted mean based on 1983 heart transplant volume, as reported in Chapter 3. The weights were as follows: Arizona--.0725, Columbia--.1884, MCV--.1449, Minnesota--.1014, Pittsburgh--.2101, and Stanford--.2826.

[c]For this line only, it is assumed that each center had professional fees (for radiology, pathology, pulmonary physicians and others) of $1250. This amount is substituted for the mean professional fees shown above. As explained in the text, charges by surgeons, anesthesiologists, and cardiologists are considered separately.

Table 28-8
Mean Charges and Days for Transplant Hospitalization
for Those Discharged Dead, by Center

CHARGE CATEGORY	CENTER						
	ARIZONA	COLUMBIA	MCV	MINNESOTA	PITTSBURGH	STANFORD	ALL
SUPPLIES	$ 5,083	100	4,271	4,525	2,677	11,918	--
OR & ANESTHESIA	2,710	5,273	3,785	4,568	14,841	8,994	--
PHARMACY	5,660	3,597	5,194	10,763	3,361	13,081	--
THERAPY	3,987	1,246	2,851	695	667	3,594	--
APPLIANCES	1,445	441	-0-	-0-	1,156	-0	--
DIAGNOSTIC TESTS	2,990	6,631	2,479	9,841	3,860	7,438	--
BLOOD ADM.	2,112	4,674	3,482	4,021	3,989	2,298	--
OXYGEN & GAS	-0-	96	1,251	237	-0-	-0-	--
LAB TESTS	9,974	10,083	6,440	9,560	8,717	37,456	--
OTHER & MISC.	274	457	1	299	323	-0-	--
PROF. FEES	12,601	25,413	1,880	835	1,104	2,599	--
ROOM AND BOARD	9,634	18,979	10,328	10,570	12,187	72,851	--
TOTAL	$56,471	76,991	41,963	55,915	52,881	161,582	--
(Std. Dev.)	(42,120)	(44,495)	(46,516)	(44,354)	(37,986)	(103,561)	--
ADJUSTED TOTAL	$45,120	52,828	41,333	56,330	53,027	160,233	$81,348
HOSPITAL DAYS							
ICU or CCU	12.5	17.0	15.3	14.3	9.0	64.2	--
General Ward	5.5	9.1	9.6	3.1	13.8	13.2	--
Total - Mean	18.0	26.1	24.9	17.4	22.8	77.5	38.3
NO. OF OBSERVATIONS	8	10	8	8	12	20	66

[a]All charge estimates are in 1983 dollars. Histocompatibility lab charges and heart acquisition costs are not included. Number of observations applies to mean total charges. Other lines may differ because of missing values.

[b]This is the weighted mean based on 1983 heart transplant volume, as reported in Chapter 3.

[c]For this line only, it is assumed that each center had professional fees (for radiology, pathology, pulmonary physicians and others) of $1250. This amount is substituted for the mean professional fes shown above. As explained in the text, charges by surgeons, anesthesiologists, and cardiologists are considered separately.

patients who died after a very lengthy and expensive stay. Interestingly, the use of intensive care varies considerably across centers. The adjusted total charges for survivors are in the range of $52,000 to $90,000 and have much smaller relative standard deviations than do the adjusted total charges for decedents. The mean charges for Stanford decedents in Table 28-8 are about $160,000 while all the other centers fall between $41,000 and $56,000. The source of this difference is a small number of cases at Stanford with very long, expensive stays.

Comparisons in total charges across centers could be somewhat misleading because Stanford had so many more patients prior to 1983 than the other centers. Stanford has reported its average length of stay to be falling over time. This makes it somewhat surprising that the survivors at Stanford have shorter average length of stay than several of the other centers.

The fact that average length of stay at Stanford for decedents is much longer than the other centers is due to a few patients with very long post-transplant stays and very large associated expenses. With only 20 observations, these few raise costs considerably. It is unclear whether this represents some difference in philosophy across centers or whether the other centers, averaging much shorter stays, have had a different case mix. Weighting by the 1983 heart transplant volume, the total charge for decedents exceeds that for survivors by about $10,000. This differential could easily move in the other direction in the future if the Stanford experience is atypical.

To determine what the costs would have been to Medicare for these patients requires several computational steps. First, the charges and hospital days for each patient were multiplied by the Medicare cost-to-charges ratio and the per diem costs, respectively. These factors are presented in Appendix Tables 28-A-1 through 28-A-6. As discussed in the appendix, this conversion to costs is approximate, since it proved impossible to assign hospital bills retrospectively to the correct Medicare Cost Report categories. Furthermore, rough imputations had to be made because of the unavailability of data.

The second step requires transforming these cost estimates to constant dollars. This was done by inflating historical costs using the medical care component of the Consumer Price Index for the years 1978-83. 1983 was chosen as the base year for this conversion. These two steps yield the cost estimates shown on the top panel of Table 28-9. Mean costs for survivors are $61,657 and for decedents $66,827. Again, the latter is strongly influenced a few high cost outliers at Stanford.

Third, the patient's share of these costs must be subtracted. In principle, this could be done patient-by-patient for the rules in effect at the time. A less cumbersome and perhaps more reliable method, was simply the application of the deductible and copayment in effect in 1983. The deductible was $304, and the copayment was $76 per diem for days hospitalized more than 60 days in a benefit period and $152 per diem for more than 90 days (but less than 150). These costs to the patient were allocated based on historical experience in the six centers in terms of stays within these intervals. The mean

Table 28-9
Computation of Medicare Costs for Transplant Hospitalization

I. MEAN COSTS TO MEDICARE BY CENTER (before patient cost-sharing)

	CENTER						
	ARIZONA	COLUMBIA	MCV	MINNESOTA	PITTSBURGH	STANFORD	ALL[b]
Survivors: Mean	$51,879[a]	72,785[a]	53,477	54,367	47,476	74,122	61,657
Decedents Mean	$33,750	43,398	36,926	47,816	38,988	133,804	66,827

II. COSTS TO MEDICARE AFTER PATIENT COST-SHARING

	All	-	Patient Share	=	Medicare Cost
Survivors	$61,657		$926		$60,731
Decedents	$66,827		$895		$65,932

[a]Costs exceeded charges, so charges were used.

[b]Weighted means based on 1983 transplant volume.

[c]Patient share is based on deductible of $304 plus per diem of $76 for stays of longer than 60 days but less than 90 days, and of $152 for stays between 90 and 150 days.

share would be $926 for survivors and $895 for decedents. In other words, patients are assumed to pay some one-to two percent of costs on average. Of course, the bill would be substantial to those with very long stays. This yields the average inpatient cost to Medicare shown on the second part of the table. The mean across all centers is used as the estimate in the base case. The mean cost to HCFA for survivors was $60,731 and for decedents it was $65,932.

b. Organ Procurement Costs. The six centers were asked to provide information on the costs of heart procurement for all patients transplanted at their institution between January 1, 1978 and June 30, 1983. The available information was not as complete as that available for hospitalization. This is true because of the special treatment of organ procurement under Medicare and because heart procurement has been of minor consequence at the centers when compared with the volume of kidney procurement.

Garrison (1983) provides a discussion of issues involved in estimating the costs of procuring hearts as well as a description of the procurement process. It is assumed in this analysis that HCFA will reimburse heart procurement on a cost pass-through basis, as it currently does kidney procurement.

Table 28-10 summarizes the data gained from the centers. Only three of the centers reported detailed costs for procurement, and only 43 observations were available. (Other centers reported aggregate costs per organ procured, but because of time and other limitations, these observations have not been utilized.) The overall mean charge was $4,853, with a range of $1,716 to $18,329. Medicare

Table 28-10
Derivation of Heart Procurement Costs

I. HISTORICAL CHARGES BY CENTER

	Mean Charges	Number of Observations
Columbia	$3,463	7
Minnesota	3,790	7
Stanford	5,445	29
Total	$4,853	43

II. ASSUMED COSTS TO HCFA[a]

$4853 x .65 = $3,154

[a]Uses average national cost-to-charges ratio of .65 since heart procurement is from other hospitals.

reimburses kidney procurement on an average cost basis. In 1981 (HCFA, 1983) the mean cost of procuring a kidney was $7,125. This suggests that the heart procurement estimates are somewhat less. But this may be because surgical fees are not included. In this analysis, surgical fees for cardiectomy are included in transplant period physicians fees. The base case estimate assumes $4,853 in charges per organ procured. Using the overall Medicare costs-to-charges ratio of .65, because procurement is at other hospitals, implied costs are $3,154. This may be an understatement for purposes of the future, since programs have apparently often received donated transportation in the past. But the vast majority of these 43 observations show some transport charges.

c. Physician Services. Estimating the costs of physician services used during the transplant period is problematical. In the past, the programs were funded with grants and therefore no charges or costs were directly associated with procedures. In addition, physician billing is usually separate from hospital billing. A complete accounting would require tracking down each patient's particular physician or physicians.

In lieu of such a complex data collection effort, each transplant center was sent a questionnaire (see Appendix 28-B) regarding the costs of physician services to recipients. Not all the responses were complete or usuable. Generation of an estimate therefore relies on a composite of their responses. Table 28-11 summarizes the derivation of these estimates.

Table 28-11
Derivation of the Costs of Physician
Services Associated with Transplantation

I. CHARGES REPORTED ON QUESTIONNAIRE.

1. Surgical fees for cardiac transplant:	
- Stanford University - global fee - includes removal donor heart and - all pre- & post-op care	$10,000
- Columbia - global fee (+ $5750 for co-surgeon, if used) - includes pre- & post-op care	$11,500
- Arizona - sum of itemized charges - includes post-op care and heart procurement	$10,350
- Minnesota - global fee - includes pre-op and post-op care	$ 4,015
- Pittsburgh - transplant and cardiectomy	$6,720
2. Anesthesiologist fees:	
- Stanford (includes procurement) - $1800 for transplant; $800 cardiectomy	$ 2,600
- Columbia (for transplant)	$ 2,000
- Arizona ($25 per each 15 minutes)	varies
3. Cardiologist fees:	
- Stanford - ECG (3 per week)	$ 200-300
- Catheterization (1 per recipient)	$ 190
- Columbia - ($60 visit per day)	$ 1,000-2,000
Cath. ($500 each/1 per week)	$ 2,000-4,000
- Pittsburgh - Biopsy ($218 each/1 per week)	$ 1,000-2,000
4. Other physicians	
- Stanford	
- Pathologist	$350-500
- Blood bank	$150-200
- Columbia - Pathologist ($75/biopsy)	

II. IMPLIED COSTS TO HCFA

Item	Assumed Charge	Implied Cost
1. Surgeon fees	$10,000	8,000
2. Anesthesiology	2,000	1,600
3. Cardiology	2,000	1,600
4. Other Physician Charges	1,250	1,000

[a]Uses Medicare Part B coinsurance rate of 80 percent. The other physician costs of $1000 included in hospital costs.

As the figures in Table 28-11 suggest, it proved difficult to reconcile the differences across centers. Some itemize fees and others charge global fees. Not all centers use the same mix of physicians by specialty either. It was assumed that surgeon fees come to $10,000, including all pre- and post-operative care, the transplant operation, and the donor cardiectomy. This is considerably above the reported charge reported for triple coronary bypass of $3,800-6,000 at these centers. Anesthesiologist fees were assumed to be $2,000, based on reports from two centers. Cardiologist fees were assumed to total $2,000 for biopsies with catheterization on a more or less weekly basis and for inpatient visits. Differences in the reports across centers make this difficult to estimate.

Charges for other physician services represent services by hospital-based physicians that frequently show up on hospital bills. This $1,250 has been incorporated into the means in Tables 28-7 and 28-8. Finally, other physicians--otolargyngologists, neurologists, infectious disease specialists--will provide service on an as needed basis. No attempt is made to include these separately because no good estimate was available and because they may be reflected to some degree in the $1,250 for other physician charges.

In sum, total physician charges are estimated to be $15,250 on average during the transplant period. It should be obvious from the methods used that considerable uncertainty surrounds this figure. The method of adding up routine, reported items probably leads to some underestimating, though the relative magnitude may not be large.

d. Summation of Transplant Period Cost Items. Table 28-12 shows how the three costs discussed above--inpatient hospital costs, organ procurement costs, and physician services costs--are combined to produce an estimate of total costs for the base case. There are two key figures--$75,085 for survivors and $80,286 for decedents--that are input to the cost-effectiveness analysis and cost projections.

The distinction between those discharged alive and those dead is maintained only for hospitalization costs. Costs for heart procurement and physician services are simply added directly to these. This is not a bad assumption given that the average charges used are global fees not distinguishing between care to these two groups. Organ procurement costs should not depend on whether the recipient eventually dies or not. Lower and upper bounds for these estimates are specified in the table as well, and depend on alternative assumptions about hospitalization cost. The lower bound uses a lower cost-to-charges ratio for hospitalization cost. The upper bound, relying on charges rather than costs, may indicate the upper limit on resource costs to society if cost-shifting is as prevalent as many believe.

3. POST-DISCHARGE PHASE COSTS

The descriptive model used here breaks the post-transplant phase into annual periods beginning with the date of discharge for those who are discharged alive. Costs are determined separately for those who survive each year and those who die. Three categories are considered: (1) hospitalization at the transplant center, (2) outpatient costs, and (3) costs of immunosuppression and other drugs.

Table 28-12
Computation of Medicare's Cost for Transplant Phase

I. BASE CASE ESTIMATES:	Survivors	Decedents
Hospitalization Cost	$60,731	$65,932
Organ Procurement	3,154	3,154
Physician Services	11,200	11,200
Total Cost	$75,085	$80,286

II. ALTERNATIVE ESTIMATES	Survivors	Decedents
Lower bound:[a]	$60,843	67,230
Upper bound:[b]	88,675	98,502

[a]Lower bound uses charges multiplied by Medicare national cost-to-charges ratio of .65 for hospitalization cost.

[b]Upper bound uses charges for hospitalization cost and for physician services.

Only the first category relies on information both for those who lived and those who died in a year following transplantation. The latter three categories rely on report by living recipients. This selection bias creates potential problems for interpretation which are discussed in the text. However, to this point the basic stance has been to overlook these difficulties on the grounds that the bias is not significant in terms of overall program effects.

a. Post-Discharge Hospitalization. Hospitalization after discharge following a successful transplant can occur at either the transplant center or at some other hospital, perhaps one closer to the recipient's home. The former admissions are much easier to track than the latter. As part of the records abstraction (described in Chapter 6), the NHTS requested the complete post-discharge hospitalization history for all recipients at the six centers. The admission date, discharge date, and reason for hospitalization were coded for each hospitalization at the transplant center. Using those histories with complete information, the average number of days per year post-transplant were computed for those who survived a post-transplant year and for those who died in a post-transplant year. The resulting estimates are shown in the first two columns of Table 28-13.

The average recipient who dies during the first year post-discharge spends 30.5 days in the transplant center hospital. Recipients surviving the first year post-discharge spent 19.7 days in the hospital. The unstable pattern in later years is due in part to small sample size.

Table 28-13
Mean Days Hospitalized per Year by Year
Post-Discharge and by Survival and Implied Costs[a]

Post-Discharge Year	Mean Days for Recipient Living Complete Year	Mean Days for Recipient Dying During Year	Implied Costs[b] Survivor	Implied Costs[b] Decedent
First	19.7 (113)	30.5 (82)	$6,718	$10,401
Second	7.7 (77)	34.8 (9)	2,626	11,867
Third	12.6 (53)	11.6 (8)	4,297	3,956
Fourth	11.7 (35)	12.6 (8)	3,990	4,297
Fifth thru Eighth	9.9 (58)	29.3 (6)	3,376	9,991
Second thru Eighth	10.1 (223)	22.0 (31)	$3,444	$7,502

[a]Number of observations in parentheses.

[b]Based on assumed cost of $341 per day for hospital and physician services. See text for explanation.

Although the NHTS has collected cost data for some of these hospitalizations, the data have not yet been coded and linked to these stays. As an approximation, at this point, the annual days per year are multiplied by the average cost per day experienced by disabled Medicare beneficiaries in the first six months of 1983 (HCFA, 1984). Mean charge per day was $487, but HCFA bore only 65.0% of this or $316.5. The implied costs per day assume an additional charge of $30 per day for physician services, which is probably an underestimate. According to AMA (1983) figures, internists charged $27 per follow-up hospital visit in 1982. Because of the instability in the estimates, years two through eight are pooled to compute the base case estimate. Costs for post transplant years after the first year are $3,444 per year for survivors and $7,502 for decedents.

Estimating post-discharge hospitalization at centers other than the transplant centers raises another set of difficulties. The data are readily available only from living recipients, but must be based on their recall. In the living recipient survey (discussed in Chapter 5), each recipient was asked for days of stay and hospital expenses in the past year for hospitalization not at their transplant center. Such self-report data suffer from some obvious limitations. Yet they provide the only basis available in the NHTS for approximating these costs.

Table 28-14 summarizes the reports of living recipients on the annual hospital expenses and days of care are reported by year post-discharge. Again, because of the variability in the year-to-year estimates, the overall mean is used in the calculation. Multiplying

Table 28-14
Post-Discharge Costs of Living Recipients at Other Hospitals[a]

Year Post-Discharge	Mean Days Per Year	Mean Reported Hospital Expenses Per Year	Estimated[b] Mean Costs Per Year
Less than One	5.0 (37)	--	--
First	2.1 (34)	--	--
Second	1.8 (25)	--	--
Third	10.4 (9)	--	--
Fourth	3.1 (7)	--	--
Fifth	2.7 (10)	--	--
Sixth thru Tenth	4.1 (18)	--	--
All years	3.7 (140)	$1,651 (140)	$1,073

[a]Number of observations in parentheses.
[b]Expenses multiplied by national Medicare cost-to-charges ratio of .65.

this by the Medicare national average cost-to-charges ratio of .65 yields an annual cost of $1,073. It should be remembered that this estimate is subject to at least two biases. First, since the survey is of living recipients, the average number of days will be understated if those who die spend more days in hospitals other than the transplant center. Second, a further understatement may occur since those with less than one year of post-discharge experience were counted as having one year. Adjustment for this latter problem has not been undertaken because of time limitations. Correcting for the former selection bias would be made more difficult. In any case, the impact of either on total costs to Medicare is unlikely to be important.

b. Post-Discharge Outpatient Expenses. Post-discharge expenditures for outpatient physician services and tests were also estimated relying on the survey of living recipients. Therefore, some of the same biases exist. The estimated expenses for visits in the past year to physicians other than routine heart-related checkups are shown in column one of Table 28-15. Because of the small number of cases and unstable pattern, use of these figures year-by-year as shown would be questionable. Instead, the overall mean is used in subsequent calculations.

The second column shows the mean expenses per year reported by living recipients for routine visits to their cardiologist. These charges are summed and multiplied by the Medicare share (.8) to obtain the annual costs shown in the third column. Note again that these estimates do not differentiate between living and dying patients. Given the observed pattern and that the modal values were 12 visits

Table 28-15
Post-Discharge Outpatient Expenses
by Year Post-Discharge

I. ESTIMATES FROM SURVEY OF LIVING RECIPIENTS

Year Post-Discharge	Mean Annual Expenses for Nonroutine Physician Care	Mean Annual Expenses for Routine Care
Less than One	$672 (10)	$3,941 (29)
First	163 (7)	1,678 (25)
Second	969 (15)	566 (19)
Third	175 (4)	642 (6)
Fourth	75 (4)	616 (6)
Fifth	235 (6)	502 (8)
Sixth thru Tenth	80 (14)	783 (12)
All years	$502 (50)	--

II. ASSUMED PARAMETER VALUES

Year Post-Discharge	Mean Annual Expenses for Nonroutine Physician Care	Mean Annual Expenses for Routine Care	Mean Total Costs for Outpatient Physician Care
First	$502	1,678	$1,744
Second through Tenth	502	600	$ 882

[a]Number of observations in parentheses.

[b]Based on modal values: twelve visits per year at $50 each.

per year and $50 per visit, assumed fees of $600 per year are used for years two through ten in later calculations. Routine expenses in the first year post-transplant are assumed to be $1,678, which is the mean for the sample. This difference is maintained on the grounds that first-year follow-up by centers involves more extensive testing.

c. Post-Transplant Drug Costs. In this section, estimates of charges for outpatient drugs are reported based on results for the living recipients. Note that, for the base case, these are not included as costs to Medicare, though their potential coverage is discussed in the sensitivity and simulation analyses presented in Chapters 29 and 30.

Table 28-16 shows the average expense for the past year for immunosuppressive drugs and for other drugs (prescription or nonprescription). The mean expense for immunosuppressive drugs was $810 per year and for nonprescription drugs was $297. This means that, under current Medicare provisions, the patient would spend $1,107 in drug expenses out-of-pocket each year. Note that the mean for immunosuppressive drugs is well below the $10,000-$11,000 per year that might possibly be charged if cyclosporine is the drug of choice.

d. Summation of Post-Discharge Costs. Table 28-17 shows the result of adding together the estimates in Tables 28-13 through Table 28-15. The base case estimates are for costs and the high estimates for charges. First year costs are higher than subsequent year costs by about $3,000 for both survivors and decedents, and decedents' costs exceed survivor costs by about $2,500 in each year. Because of the methods used and assumptions made, the differences between survivors

Table 28-16
Drug Expenses by Year Post-Discharge for Living Recipients[a]

Year Post-Discharge	Mean Annual Immunosuppressive Drug Expense	Mean Annual Other Drug Expense	Total[b]
Less than One	$ 803 (20)	$ 359 (27)	$1,162
First	1,266 (21)	524 (27)	1,790
Second	692 (16)	144 (19)	836
Third	235 (2)	186 (9)	421
Fourth	350 (6)	23 (7)	373
Fifth	1,100 (5)	428 (4)	538
Sixth thru Tenth	86 (7)	56 (13)	142
All Years	$ 810 (77)	$ 297 (111)	$1,107

[a]Number of observations on parentheses.

[b]Sum of columns one and two.

Table 28-17
Derivation of Estimates for Post-Discharge Costs and Charges

I. BASE CASE: COST ESTIMATES

Post-Discharge Year	Care Component	Survivors	Decedents
First	Transplant Center	$6,718	$10,401
	Other Hospitals	1,073	537
	Outpatient	1,744	872
	Total	$9,535	$11,810
Second through Tenth	Transplant Center	$3,444	$ 7,502
	Other Hospitals	1,073	537
	Outpatient	1,744	872
	Total	$6,261	$ 8,911

II. HIGH ESTIMATES: CHARGES

Post-Discharge Year	Care Component	Survivors	Decedents
First	Transplant Center	$10,185	$15,769
	Other Hospitals	1,651	825
	Outpatient	2,180	1,090
	Total	$14,016	$17,684
Second through Tenth	Transplant Center	$ 5,222	$11,374
	Other Hospitals	1,651	825
	Outpatient	1,102	551
	Total	$ 7,975	$12,750

[a]These estimates are the unweighted summation of the post-discharge costs in Tables 28-13 through 28-15. Note that the decedents were only considered to incur one-half the expenses shown in Tables 28-14 and 28-15 because they are presumed to live only one-half year in the relevant period.

and decedents are determined primarily by days hospitalized at transplant center. Because of assumptions made about (1) costs per day at the transplant center and (2) the costs of decedents at other hospitals (same rate as the survivors), these costs may well be understated.

F. SUMMARY AND LIMITATIONS

In the preceding section the derivation of the costs to HCFA by phase was described in detail. These resulting parameter estimates, which are used in Chapters 29 and 30, are summarized in Table 28-18. The transplant procedure itself costs approximately $75,000. Evaluations cost about $3,700, and the costs of keeping the patient alive while awaiting the transplant are high--$6,151 per month. Costs in years post-discharge depend on survival status but range between $6,000 and $12,000 per year.

Clearly, the heart transplant procedure itself is very expensive. The crucial question is, of course, the extent to which other costs would have been incurred for these beneficiaries otherwise. Recall that the base case assumes that costs while awaiting transplant would have been incurred anyway, so that the net cost to HCFA is small. But $6,151 per month of alternative survival (after the day of transplant) is substantial, and the method used here to make that projection is admittedly crude. The framework, assumptions, and estimates are presented in detail in the spirit that the reader can experiment with alternative assumptions.

Table 28-18
Summary of Parameter Estimates for
Medical Costs to HCFA

Phase and Element	Base Case	Range Low	Range High
I. PRE-TRANSPLANT			
A. Evaluation Cost	$ 3,700	$2,700	$5,200
B. Candidacy Cost (per month)	$ 6,151	$1,000	--
II. TRANSPLANT PERIOD COSTS			
A. Survivors	$75,085	60,843	88,675
B. Decedents	$80,286	67,230	98,502
III. POST-DISCHARGE ANNUAL COSTS			
A. First Year:			
- Survivors	$ 9,535	--	$14,016
- Decedents	$11,810	--	$17,684
B. Second Year and Beyond			
- Survivors	$ 6,261	--	$ 7,975
- Decedents	$ 8,911	--	$12,750

Although the base case estimate was intended to represent the most likely parameter values, a reasonable argument can be made that in some instances the methods used may bias the estimates. For example, reliance on national costs per day and on the recall of living recipients may understate the costs of post-discharge care. Or the use of candidacy costs of recipients prior to transplant may overstate the mean costs per month after that point had no transplant been done. Generally speaking, estimates of costs during the transplant period are probably more reliable than either pre-transplant or post-discharge estimates. This is somewhat comforting since the bulk of costs fall in this interval. Yet, Finkler (1982) reminds us not to abandon caution in using hospital charge data since reimbursement systems are designed in large part to maximize revenues and not to reflect costs to society. Indeed, costs to HCFA are not necessarily, nor even probably, costs to society. If one sides with those who believe that substantial cost shifting has occurred from Medicare to other providers, then the estimates may be below the resource costs to society. Perhaps Medicare costs and hospital charges could be thought of as lower and upper bounds, respectively, on the resource costs to society.

Although a number of limitations in the analysis were alluded to in the presentation of the results, it is important to reiterate a number of them. These include:

1. The focus on medical costs to HCFA rather than medical costs to society.

2. The fact that nonmedical social costs are not included in the analysis.

3. The problem of using a weighted historical average as the base case assumption.

4. The reliance on living recipients for many parameter estimates, without correction for selection bias.

5. The difficulty of gathering comparable data across centers on physician fees.

6. The lack of attention to the impact on costs to HCFA under Medicaid coverage or under the new prospective payment system.

7. The lack of a good estimate of the costs that would have been incurred without the transplant.

Some of these limitations, for example the first two, are not so much a fault as a warning about factors affecting interpretation. The final limitation is the most severe and problematic. Future efforts would do well to focus on overcoming it.

Finally, as mentioned at points in the text, because of time limitations, this analysis was not able to utilize all the information on costs gathered in the NHTS. Most notably, data collected on candidates who died awaiting a transplant has not been incorporated, nor has detailed post-discharge data on recipients. Furthermore, the sources of differences among patients and centers have not been explored. These compromises probably do not substantially affect the results for the purpose of projecting costs to HCFA. But there remains much that can be learned about the costs of heart transplantation from further analysis of the NHTS data.

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APPENDIX 28-A

CALCULATION OF INPATIENT MEDICARE COSTS IN THE NATIONAL HEART TRANSPLANTATION STUDY

Appendix 28-A

Calculation of Inpatient Medicare Costs in the National Heart Transplantation Study

In the National Heart Transplantation Study bills were collected from the six participating hospitals for all recipients or potential candidates since January 1, 1978. These billings show the summary of charges by cost center for each hospital stay (see Figure 28-A-1 for example). In general, these charges exceed the costs that would have been paid by Medicare if heart transplantation had been a covered service at the time. To determine what the costs would have been to Medicare under hypothetical coverage, it is necessary to develop the relevant per diem costs and ratios of costs to charges. The original bills are then multiplied by these entries to obtain the costs to Medicare.

These ratios and per diem costs were abstracted from the Medicare Cost Reports for each institution for each year. These reports show only the provider's explanation of the appropriate settlement; the actual settlement may vary slightly, but variance is assumed to be minor. The purpose of this appendix is to describe briefly where each relevant element is found in the Medicare Cost Report and to present the factors used in the actual conversion. These are the three major categories of costs: ancillary costs, intensive care costs, and routine service costs.

Figure 28-A-1

Typical Summary Sheet for Hospital Bill

MEDICAL COLLEGE OF VIRGINIA HOSPITALS
VIRGINIA COMMONWEALTH UNIVERSITY

P.O. BOX 26728
RICHMOND, VA. 23261
(804) 786-0590

SUMMARY BY SERVICE

12	DAYS	@ 166.00	ROOM & CARE (PRIVATE)	1992.00
25	DAYS	@ 168.00	ROOM & CARE (PRIVATE)	4200.00
74	DAYS	@ 163.00	ROOM & CARE (SEMI-PVT)	12062.00
11	DAYS	@ 450.00	ROOM & CARE (ICU)	4950.00
122			TOTAL DAYS	23204.00
9			OPERATING ROOM SERVICE	2644.21
19			OPERATING ROOM SUPPLIES	1829.93
6			ANESTHESIA SUPPLIES	762.00
957			PHARMACY	13719.19
8			DISCHARGE DRUGS	144.38
69			X-RAY DIAGNOSTIC	2151.00
5			NUCLEAR MEDICINE	1303.00
656			LABORATORY	9570.17
112			MED/SURG SUPPLIES	834.82
10			PULMONARY FUNCTION	320.00
9			INHALATION THERAPY	257.00
51			PHYSICAL THERAPY	658.00
19			OCCUPATIONAL THERAPY	610.00
3			EKG	105.00
4			CARDIAC MONITORING	960.00
136			TOTAL MEDICAL	35868.70
			TOTAL CHARGES	59072.70

IE GUARANTOR IS RESPONSIBLE FOR FULL PAYMENT
F THE BILL AMOUNT BILLED TO INSURANCE IS ONLY
N ESTIMATE. MAKE REMITTANCE PAYABLE TO VCU
CV HOSPITALS. MAIL TO ADDRESS SHOWN AT TOP OF
HIS BILL.
HIS BILL DOES NOT INCLUDE THE FEES OF YOUR
YSICIAN

	ACCOUNT BALANCE	ESTIMATED INSURANCE COVERAGE			PLEASE PAY THIS AMOUNT
		COMPANY 1	COMPANY 2	COMPANY 3	
TOTALS					

PATIENT NAME

ACCOUNT NUMBER

A776 H FIN-T-8 (3/26/78)

PLEASE KEEP THIS STATEMENT FOR YOUR RECORDS. THERE WILL BE A CHARGE FOR ADDITIONAL COPIES.

Ancillary Costs

The ratios of cost to charges for ancillary cost centers can be found on Worksheet C, lines 1 through 27, column 2 (see Figure 28-A-2). These must be multiplied by the corresponding total charges for each cost center, and summed to yield total ancillary costs for the patient. Correspondence may be complicated if the billing cost centers differ from the Medicare report cost centers, as is true for the six transplant centers.

Intensive Care Costs

The Medicare Cost Report contains the average cost per diem by type of intensive care unit. These are shown as column 3, lines 39-42 on Worksheet D-1, Part I (see Figure 28-A-3). Again, these are multiplied by the corresponding ICU days shown on the summary bill of the patient. (The actual ICU charges to the patient are ignored in making this calculation.)

Routine Service Days. Costs per diem for stays in semi-private rooms are more complicated to establish than for ICU days because of some excludable costs and cost limitations. To establish costs per routine day requires the following division:

$$\frac{\text{Reimbursable General Inpatient Routine Service Cost (i.e., Worksheet D-1, Part 1, Line 38 Column 1)}}{\text{Total Inpatient Days Applicable to Title XVIII, Part A (i.e., Worksheet D-1, Part 1, Line 8 Column 1)}}$$

See Figure 28-A-3 for the numerator, and Figure 28-A-4 for the denominator.

Figure 28-A-2

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DEPARTMENTAL COST DISTRIBUTION

PROVIDER NO.. _____ PERIOD FROM _____ TO _____

WORKSHEET C

	COST CENTER		TOTAL (From Wkst. B, Col. 21)	RATIO OF COST TO CHARGES	INPATIENT: HOSPITAL (COL. 2 × 3b)	INPATIENT: SUBPROVIDER I (COL. 2 × 4b)	INPATIENT: SUBPROVIDER II (COL. 2 × 5b)	INPATIENT: SKILLED NURSING FACILITY—CERTIFIED (COL. 2 × 6b)	TITLE XVIII OUTPATIENT: PART B 100% (COL. 2 × 7b)	TITLE XVIII OUTPATIENT: PART B OUTPATIENT EMERGENCY SERVICE (COL. 2 × 8b)	
			1	2	3	4	5	6	7	8	
1	**ANCILLARY SERVICE COST CENTERS**										1
2	Operating Room	a	$		$	$	$	$	$	$	2
		b	$		$	$	$	$	$	$	
3	Recovery Room	a	$		$	$	$	$	$	$	3
		b	$		$	$	$	$	$	$	
4	Delivery Room & Labor Room	a	$		$	$	$			$	4
		b	$		$	$	$			$	
5	Anesthesiology	a	$		$	$	$	$	$	$	5
		b	$		$	$	$	$	$	$	
6	Radiology—Diagnostic	a	$		$	$	$	$	$	$	6
		b	$		$	$	$	$	$	$	
7	Radiology—Therapeutic	a	$		$	$	$	$	$	$	7
		b	$		$	$	$	$	$	$	
8	Radioisotope	a	$		$	$	$	$	$	$	8
		b	$		$	$	$	$	$	$	
9	Laboratory	a	$		$	$	$	$	$	$	9
		b	$		$	$	$	$	$	$	
10	Whole Blood and Packed Red Blood Cells	a	$		$	$	$	$	$	$	10
		b	$		$	$	$	$	$	$	
11	Blood Storing, Processing & Transfusion	a	$		$	$	$	$	$	$	11
		b	$		$	$	$	$	$	$	
12	Intravenous Therapy	a	$		$	$	$	$	$	$	12
		b	$		$	$	$	$	$	$	
13	Oxygen (Inhalation) Therapy	a	$		$	$	$	$	$	$	13
		b	$		$	$	$	$	$	$	
14	Physical Therapy	a	$		$	$	$	$	$	$	14
		b	$		$	$	$	$	$	$	
15	Occupational Therapy	a	$		$	$	$	$	$	$	15
		b	$		$	$	$	$	$	$	
16	Speech Pathology	a	$		$	$	$	$	$	$	16
		b	$		$	$	$	$	$	$	
17	Electrocardiology	a	$		$	$	$	$	$	$	17
		b	$		$	$	$	$	$	$	
18	Electroencephalography	a	$		$	$	$	$	$	$	18
		b	$		$	$	$	$	$	$	

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DEPARTMENTAL COST DISTRIBUTION — Continued

			1	2	3	4	5	6	7	8	
19	Medical Supplies Charged to Patients	a	$		$	$	$	$	$	$	19
		b	$		$	$	$	$	$	$	
20	Drugs Charged to Patients	a	$		$	$	$	$	$	$	20
		b	$		$	$	$	$	$	$	
21	Renal Dialysis	a	$		$	$	$	$		$	21
		b	$		$	$	$	$		$	
22		a	$		$	$	$	$	$	$	22
		b	$		$	$	$	$	$	$	
23		a	$		$	$	$	$	$	$	23
		b	$		$	$	$	$	$	$	
24	**OUTPATIENT SERVICE COST CENTERS**										24

Figure 28-A-3

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COMPUTATION OF INPATIENT ROUTINE SERVICE COST	PROVIDER NO.:	PERIOD FROM TO	WORKSHEET D-1

PART I — TITLE XVIII (Medicare)

MEDICARE GENERAL INPATIENT ROUTINE SERVICE COST

		HOSPITAL	SUBPROVIDER I	SUBPROVIDER II	SKILLED NURSING FACILITY	
		1	2	3	4	
29	Depreciation allocated to general inpatient routine service (From column 21, line 25.46 [hospital]; line 25.49 and/or line 25.50 [subprovider]; line 25.52 [skilled nursing facility])	$	$	$	$	29
30	Cost of approved medical education programs (From Wkst. B, sum of columns 18 and 19, line 46 [hospital], lines 49 and/or 50 [subprovider])					30
31	Total cost to be excluded from general inpatient routine service cost (sum of lines 29 and 30)	$	$	$	$	31
32	Per diem for excludable cost (line 31 ÷ line 3)	$	$	$	$	32
33	Medicare excludable cost (line 32 × line 8)	$	$	$	$	33
34	General inpatient routine service cost for comparison to cost limitation (line 24 minus line 33)	$	$	$	$	34
35	General inpatient routine service cost limitation (line 8 × $ per diem limitation [hospital/subprovider]; line 8 × $ per diem limitation [skilled nursing facility])	$	$	$	$	35
36	Aggregate charges for excess cost applicable to kidney acquisition (From page 3, Part II, line 10h or page 4, Part IV, line 10h × $ per diem charge)	$	$	$		36
37	TOTAL (Sum of lines 35 and 36)	$	$	$	$	37
38	Reimbursable general inpatient routine service cost (If line 34 is less than line 37, enter the sum of lines 33 and 34) (If line 37 is less than line 34, enter the sum of lines 33 and 37)	$	$	$	$	38

INTENSIVE CARE TYPE INPATIENT HOSPITAL UNITS

	INTENSIVE CARE TYPE INPATIENT HOSPITAL UNITS	TOTAL INPATIENT COST	TOTAL INPATIENT DAYS	AVERAGE PER DIEM (COL 1 ÷ COL 2)	MEDICARE DAYS	COST APPLIC TO MEDICARE (COL 3 × COL 4)				
		1	2	3	4	5				
39	Intensive Care Unit	$		$		$				39
40	Coronary Care Unit	$		$		$				40
41		$		$		$				41
42		$		$		$				42
43	TOTAL MEDICARE INPATIENT GENERAL ROUTINE AND INTENSIVE CARE TYPE INPATIENT HOSPITAL (Sum of lines 38–42) (Transfer to Worksheet E, Part 1, column as appropriate, line 3)					$	$	$	$	43

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Figure 28-A-4

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COMPUTATION OF INPATIENT ROUTINE SERVICE COST	PROVIDER NO.:	PERIOD: FROM TO	WORKSHEET D-1 PART I

PART 1 — TITLE XVIII (MEDICARE)

GENERAL INPATIENT CARE UNITS (EXCLUDING NURSERY) COST

INPATIENT DAYS

		Hospital	Subprovider I	Subprovider II	Skilled Nursing Facility	
		1	2	3	4	
1	Total aged, pediatric and maternity inpatient days (Fr page 3, Pt II, col 1, line 4; page 4, Pt IV, col. as applicable, line 4)					1
2	Total other than aged, pediatric and maternity inpatient days (excl. newborn) (Fr pg 3, Pt II, col 1, line 5; pg 4, Pt IV, col as appl., line 5)					2
3	Total inpatient days—all patients (excl. newborn) (Sum of lines 1 & 2; must agree with pg 3, Pt II, col 1, line 6; pg 4, Pt IV, cols as appl., line 6)					3
4	Aged, pediatric and maternity inpatient days plus inpatient routine nursing salary cost differential (SEE INSTRUCTIONS)					4
5	Total adjusted inpatient days (Sum of lines 2 and 4)					5
6	Aged, pediatric and maternity inpatient days—appl. to title XVIII, Pt A (Fr pg 3, Pt II, col 1, line 10c; pg 4, Pt IV, col. as appl., line 10)					6
7	Other than aged, pediatric & maternity inpatient days—appl. to title XVIII, Pt A (Fr pg 3, Pt II, col 1, line 10f; pg 4, Pt IV, col as appl., line 10f)					7
8	Total inpatient days appl. to title XVIII, Pt A (Sum of lines 6&7; must agree with pg 3, Pt II, col 1, line 10f; pg 4, Pt IV, col as appl., line 10f)					8
	INPATIENT ROUTINE COSTS					
9	Total inpatient routine nursing salary cost (excluding nursery)	$	$	$	$	9
10	Total inpatient routine service cost (excluding inpatient routine nursing salary cost on line 9)					10
11	Total inpatient routine service cost (Sum of lines 9 and 10)	$	$	$	$	11
12	Inpatient routine nursing salary cost plus inpatient routine nursing salary cost differential (SEE INSTRUCTIONS)	$	$	$	$	12
	MEDICARE GENERAL INPATIENT CARE PER DIEM COSTS (Including the Inpatient Routine Nursing Salary Cost Differential Adjustment Factor)					
13	Adjusted avg. per diem inpatient routine nursing salary cost appl. to aged, pediatric & maternity patients incl. the inpatient routine nursing salary cost differential adjustment factor (line 12 ÷ line 5)	$	$	$	$	13
14	Average per diem inpatient routine service cost (excl. inpatient routine nursing salary cost) (Line 10 ÷ line 3)					14
15	Adjusted avg per diem inpatient routine service cost appl. to aged, pediatric & maternity patients including the inpatient routine nursing salary cost differential adjustment factor (Sum of lines 13 and 14)	$	$	$	$	15
16	Total inpatient routine services cost (line 11)	$	$	$	$	16
17	Inpatient routine service cost appl. to all aged, pediatric & maternity patients (line 1 × line 15)					17
18	Inpatient routine service cost appl. to all patients—other than aged, pediatric & maternity (line 16 minus line 17)	$	$	$	$	18
19	Avg. per diem inpatient routine service cost appl. to all patients—other than aged, pediatric & maternity (line 18 ÷ line 2)	$	$	$	$	19
	MEDICARE GENERAL INPATIENT ROUTINE SERVICE COST BEFORE ROUTINE SERVICE COST LIMITATION					
20	Medicare general inpatient routine service cost appl. to aged, pediatric & maternity patients (line 8 × line 15)	$	$	$	$	20
21	Medicare general inpatient routine service cost appl. to all patients—other than aged, pediatric & maternity (line 7 × line 19)					21
22	Total Medicare general inpatient routine service cost before reasonable cost limitation (Sum of lines 20 and 21)	$	$	$	$	22
23	Aggregate charges to beneficiaries for excess costs (From provider records) (SEE INSTRUCTIONS)	( )	( )	( )	( )	23
24	TOTAL (Line 22 minus line 23)	$	$	$	$	24

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This per diem cost can then be multiplied by routine days as reported on summary bill.

Summation and Other Issues

To obtain the total Medicare costs for each bill, all that remains is to sum the above costs. However, it is important to note that these costs are prior to the application of Medicare's deductible and coinsurance provisions. As described below, the relevant provisions could be applied on an individual patient basis to determine Medicare's share and the patient's. Note that Medicare sometimes reimburses for other hospital costs such as kidney acquisition, return on equity, and malpractice insurance. For this analyses, these items are assumed to be either inconsequential or irrelevant to heart transplantation.

Patient Deductibles and Coinsurance

The preceding calculation describes the costs as they apply to the Medicare program, but not the distribution between HCFA and the patient. In other words, these costs of covered services are not net of what the patient will pay. In order to determine HCFA's share that portion must be taken out. Under Part A, patients pay only a deductible ($304 in 1983) for all covered services used during the first 60 inpatient days of a benefit period. A copayment (of $76 per day) is required for the next 30 days of hospital care in a benefit period. If more than 90 days are used, the copayment rises (to $152 per day) as a lifetime reserve of 60 days are used up. Beyond this,

further use in a benefit period is not covered. After a person has been out of the hospital for 60 days, a new benefit period begins with next hospital admission.

A possible alternative to using the individual patient's history would be to use the hospital average. For a given hospital in a given year the average patient share of the Medicare cost can be calculated as:

$$\frac{\text{Net Deductible and Coinsurance Billed to Medicare Patients (Worksheet E, Part I, Line 21)}}{\text{Net Cost of Medicare Covered Services-Subtotal (Worksheet E, Part I, Line 15)}}$$

For purposes of this study it was deemed preferable to calculate the patient's share directly under assumptions about length of stay. Some patients, especially those who die in the first year, could face substantial personal liability under Medicare reimbursement rules. Rather than apply the rules to each of the patients in the sample, the Medicare deductible and coinsurance has been applied only to the mean or average cost estimate as developed from the aggregation of individual bills (See Table 28-9).

For outpatient care Medicare had a deductible of $75 in 1983 and patient coinsurance was 20% for expenditures above the deductible. These provisions have been applied to the mean or base case as well.

Conversion Factors for Transplant Costs

Table 28-A-1 through Table 28-A-6 show the conversion factors developed from the transplant centers' Medicare Cost Reports.

TABLE 28-A-1
CONVERSION FACTORS FOR MEDICARE COSTS--
ARIZONA

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
A. MEDICAL, SURGICAL, AND CENTRAL SUPPLIES						
A.1. MEDICAL SUPPLIES	--	--	--	--	--	--
A.2. SURGICAL SUPPLIES	--	--	--	.6191	.6736	.7805
A.3. CENTRAL SUPPLIES	--	.4547	.6730	.6191	.6736	.7805
A.4. OTHER SUPPLIES	--	--	--	--	--	.7805
A.5. TOTAL SUPPLIES	--	--	--	--	--	--
B. OPERATING ROOM AND ANESTHESIA						
B.1. OPERATING ROOM	--	1.0425	.8333	.7959	.7734	.7522
B.2. ANESTHESIA (EXCLUDING PROFESSIONAL TIME)	--	1.2946	1.1839	1.244	.4285	.3976
B.3. OTHER	--	--	--	.7959	--	--
B.4. TOTAL OPERATING ROOM AND ANESTHESIA	--	--	--	--	--	--
C. PHARMACY						
C.1. DRUGS, IN-HOSPITAL	--	.8203	.7409	.8048	.5800	.5913
C.2. DRUGS, TAKE-HOME OR DISCHARGE	--	.8203	.7409	.8048	.5800	.5913
C.3. I.V. SOLUTIONS	--	.8203	.7409	.8048	.5800	.5913
C.4. ALL OTHER DRUGS	--	--	--	--	--	--
C.5. TOTAL PHARMACY	--	--	--	--	--	--
D. THERAPY						
D.1. RESPIRATORY/INHALATION THERAPY	--	.5956	.4588	.4091	.3441	.3164
D.2. VOCATIONAL/OCCUPATIONAL THERAPY	--	1.8455	1.7184	2.3113	1.4660	1.8166
D.3. PHYSICAL THERAPY/PHYSICAL MEDICINE	--	1.1391	1.2471	1.8000	1.6346	1.0038
D.4. OTHER THERAPY	--	--	--	2.3113[a]	1.4660[a]	1.8166[a]
D.5. TOTAL THERAPY	--	--	--	--	--	--
E. APPLIANCES	--	.4547[b]	.6730[b]	.6191[b]	.6736[b]	.7805[b]

TABLE 28-A-1 (Continued)
CONVERSION FACTORS FOR MEDICARE COSTS--
ARIZONA

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
F. DIAGNOSTIC TESTS						
F.1. EKG	--	--	.5871	--	--	.5511
F.2. CARDIAC MONITORING/ CARDIAC CATH LAB	--	.7396	1.1388	1.0180	.9297	.7055
F.3 RADIOLOGY (X-RAY)	--	.9801	.8978	1.0133	.8630	.8110
F.4 RADIATION MEDICINE	--	--	--	--	--	1.2083
F.5. NUCLEAR MEDICINE	--	--	2.0218	2.5105	1.8032	1.3545
F.6 INFECTIOUS DISEASE	--	--	.9458[C]	--	--	.6647[C]
F.7 SURGICAL PATHOLOGY	--	--	--	.8431[C]	--	.6647[C]
F.8 OTHER DIAGNOSTIC TESTS	--	--	.9458[C]	.8431[C]	.7299[C]	.6647[C]
F.9 TOTAL DIAGNOSTIC TESTS	--	--	--	--	--	--
G. BLOOD ADMINISTRATION						
G.1. BLOOD TRANSFUSION	--	--	--	--	--	--
G.2. BLOOD BANK	--	--	--	--	--	--
G.3. COAGULATION LABORATORY	--	--	--	--	--	--
G.4. BLOOD PROCESSING	--	.8077	.8207	.9182	.9801	1.0156
G.5. BLOOD PLASMA (PROC)	--	--	--	--	.9801	1.0156
G.6. BLOOD ADMINISTRATION	--	--	--	--	--	--
G.7. BLOOD LAB	--	--	--	--	--	--
G.8. OTHER	--	--	--	--	.9801	1.0156
G.9. TOTAL BLOOD AND ADMINISTRATION	--	--	--	--	--	--
H. OXYGEN AND GAS MIXTURES	--	--	--	--	--	--

TABLE 28-A-1 (Continued)
CONVERSION FACTORS FOR MEDICARE COSTS--
ARIZONA

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
I. LABORATORY TESTS						
I.1 HEMATOLOGY	--	--	--	--	--	--
I.2. CHEMISTRY	--	--	--	--	--	--
I.3. IMMUNOLOGY IMMUNOPATHOLOGY	--	--	.9458	.8431	--	.6647
I.4. PULMONARY PHYSIOLOGY	--	.9008	.9458	.8431	.7299	.6647
I.5. VIROLOGY	--	--	--	--	--	--
I.6. MICROBIOLOGY	--	--	--	--	--	--
I.7. DRUG ASSAY	--	--	--	--	--	--
I.8. CLINICAL LABORATORY TESTS (IF GIVEN)	--	.9008	.9458	.8431	.7299	.6647
I.9. PATHOLOGY LAB TESTS (IF GIVEN)	--	.9008	.9458	.8431	.7299	.6647
I.10. ICU LABORATORY TESTS	--	--	--	--	--	--
I.11. OTHER LABORATORY TESTS	--	--	--	--	--	--
I.12. TOTAL LABORATORY TESTS	--	--	--	--	--	--
J. OTHER SERVICES	--	.9008[c]	--	.8431[c]	--	.6647[c]
K. MISCELLANEOUS	--	--	.6730[b]	.6191[b]	.6736[b]	.7805[b]
L. PROFESSIONAL FEES						
L.1. ANESTHESIOLOGY	--	--	--	--	--	--
L.2. CARDIOLOGY	--	--	--	--	--	--
L.3. SURGERY	--	--	--	--	--	--
L.4. RADIOLOGY	--	--	--	--	--	--
L.5. PULMONARY PHYSICIAN	--	--	--	--	--	--
L.6. OCCUPATIONAL THERAPIST	--	.8000	--	--	--	--
L.7. OTHER	--	--	--	--	--	--
L.8. OTHER	--	--	--	--	--	--

TABLE 28-A-1 (Continued)
CONVERSION FACTORS FOR MEDICARE COSTS--
ARIZONA

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
L.9. OTHER	--	--	--	--	--	--
L.10. OTHER	--	--	--	--	--	--
L.11. TOTAL PROFESSIONAL FEES	--	.8000	.8000	.8000	.8000	.8000
M. ROOM AND BOARD (COST PER DAY)						
M.1. ICU (SURGICAL)	--	390.07	415.49	510.13	642.14	683.17
M.2. ICU (OTHER)	--	--	511.12	--	--	--
M.3. CCU	--	325.11	511.12	394.99	523.01	554.64
M.4. GENERAL WARD (PRIVATE)	--	125.44	167.26	180.80	200.43	213.05
M.5. GENERAL WARD (SEMI-PRIVATE)	--	125.44	167.26	180.80	200.43	213.05
M.6. GENERAL WARD (OTHER)	--	--	--	--	200.43	213.05
M.7. OTHER	--	--	--	--	--	--

Notes:

a - Uses occupational therapy ratio.
b - Uses ratio for supplies.
c - Uses ratio for laboratory.

TABLE 28-A-2
CONVERSION FACTORS FOR MEDICARE COSTS--
COLUMBIA

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
A. MEDICAL, SURGICAL, AND CENTRAL SUPPLIES						
A.1. MEDICAL SUPPLIES	--	--	--	--	--	--
A.2. SURGICAL SUPPLIES	--	--	2.3136	2.808	4.052	--
A.3. CENTRAL SUPPLIES	1.7489	--	--	--	--	--
A.4. OTHER SUPPLIES	1.7489	--	--	--	--	4.052
A.5. TOTAL SUPPLIES	--	--	--	--	--	--
B. OPERATING ROOM AND ANESTHESIA						
B.1. OPERATING ROOM	1.0544	--	.9035	1.080	.6422	.6422
B.2. ANESTHESIA (EXCLUDING PROFESSIONAL TIME)	.7014	--	.9798	1.0635	--	--
B.3. OTHER	1.0544	--	.9035	1.080	.6422	.6422
B.4. TOTAL OPERATING ROOM AND ANESTHESIA	--	--	--	--	--	--
C. PHARMACY						
C.1. DRUGS, IN-HOSPITAL	.9943	--	.9330	1.2424	1.2749	1.2749
C.2. DRUGS, TAKE-HOME OR DISCHARGE	--	--	--	1.2424	--	--
C.3. I.V. SOLUTIONS	.9943	--	.9330	1.2424	1.2749	1.2749
C.4. ALL OTHER DRUGS	--	--	--	--	--	--
C.5. TOTAL PHARMACY	--	--	--	--	--	--
D. THERAPY						
D.1. RESPIRATORY/INHALATION THERAPY	.62877	--	.6129	.4842	.4367	.4367
D.2. VOCATIONAL/OCCUPATIONAL THERAPY	--	--	--	--	--	--
D.3. PHYSICAL THERAPY/PHYSICAL MEDICINE	.9305	--	.8979	.8265	.8516	.8516
D.4. OTHER THERAPY	1.9918[C]	--	--	--	1.2511[C]	--
D.5. TOTAL THERAPY	--	--	--	--	--	--
E. APPLIANCES	1.7489	--	2.3136	--	4.0523	4.0523

TABLE 28-A-2 (Continued)
CONVERSION FACTORS FOR MEDICARE COSTS--
COLUMBIA

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
F. DIAGNOSTIC TESTS						
F.1. EKG	.6662	--	.5983	.5297	.5676	.5676
F.2. CARDIAC MONITORING/ CARDIAC CATH LAB	1.3347	--	1.7028	1.357	.9829	.9829
F.3 RADIOLOGY (X-RAY)	.8737	--	1.2019	1.1919	1.063	1.063
F.4 RADIATION MEDICINE	.6275	--	--	--	.8345	.8345
F.5. NUCLEAR MEDICINE	.6643	--	.9292	--	1.1019	1.1019
F.6 INFECTIOUS DISEASE	--	--	--	--	--	--
F.7 SURGICAL PATHOLOGY	.5799	--	--	1.6650	1.968	1.968
F.8 OTHER DIAGNOSTIC TESTS	.5799	--	1.075	--	1.968	1.968
F.9 TOTAL DIAGNOSTIC TESTS	--	--	--	--	--	--
G. BLOOD ADMINISTRATION						
G.1. BLOOD TRANSFUSION	.4524	--	--	.5126	.5530	.5530
G.2. BLOOD BANK	.5321	--	.5623	.6016	.7726	.7726
G.3. COAGULATION LABORATORY	--	--	--	--	.5530	.5530
G.4. BLOOD PROCESSING	--	--	--	.5126	.5530	.5530
G.5. BLOOD PLASMA (PROC)	--	--	--	--	.7726	.7726
G.6. BLOOD ADMINISTRATION	--	--	--	--	.7726	.7726
G.7. BLOOD LAB	--	--	--	--	.7726	--
G.8. OTHER	--	--	--	--	--	.7726
G.9. TOTAL BLOOD AND ADMINISTRATION	--	--	--	--	--	--
H. OXYGEN AND GAS MIXTURES	--	--	.6129	--	.4367	.4367

TABLE 28-A-2 (Continued)
CONVERSION FACTORS FOR MEDICARE COSTS--
COLUMBIA

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
I. LABORATORY TESTS						
I.1 HEMATOLOGY	.5799	--	.5575	.6038	1.9681	1.9681
I.2. CHEMISTRY	.5799	--	.5575	.6038	1.9681	1.9681
I.3. IMMUNOLOGY IMMUNOPATHOLOGY	--	--	1.075	1.6650	1.9681	1.9681
I.4. PULMONARY PHYSIOLOGY	--	--	--	--	--	1.9681
I.5. VIROLOGY	.5799	--	1.075	1.6650	1.9681	1.9681
I.6. MICROBIOLOGY	.5799	--	1.075	1.6650	1.9681	1.9681
I.7. DRUG ASSAY	--	--	--	.6038	1.9681	1.9681
I.8. CLINICAL LABORATORY TESTS (IF GIVEN)	.5799	--	--	--	--	1.9681
I.9. PATHOLOGY LAB TESTS (IF GIVEN)	.5799	--	--	1.6650	1.9681	1.9681
I.10. ICU LABORATORY TESTS	--	--	--	--	--	--
I.11. OTHER LABORATORY TESTS	--	--	--	1.6650	1.9681	1.9681
I.12. TOTAL LABORATORY TESTS	--	--	--	--	--	--
J. OTHER SERVICES	.5799[d]	--	--	1.6650[d]	1.9681[d]	1.9681[d]
K. MISCELLANEOUS	1.7489[e]	--	2.3136[e]	--	4.052[e]	4.052[e]
L. PROFESSIONAL FEES						
L.1. ANESTHESIOLOGY	.8000	--	.8000	.8000	.8000	.8000
L.2. CARDIOLOGY	.8000	--	.8000	.8000	.8000	.8000
L.3. SURGERY	.8000	--	.8000	.8000	.8000	.8000
L.4. RADIOLOGY	--	--	--	--	.8000	--
L.5. PULMONARY PHYSICIAN	--	--	--	.8000	--	--
L.6. OCCUPATIONAL THERAPIST	--	--	--	--	--	--
L.7. OTHER	.8000	--	.8000	.8000	.8000	.8000
L.8. OTHER	--	--	--	--	.8000	.8000

TABLE 28-A-2 (Continued)
CONVERSION FACTORS FOR MEDICARE COSTS--
COLUMBIA

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
L.9. OTHER	.8000	--	--	--	.8000	--
L.10. OTHER	--	--	--	.8000	--	--
L.11. TOTAL PROFESSIONAL FEES	--	--	--	--	--	--
M. ROOM AND BOARD (COST PER DAY)						
M.1. ICU (SURGICAL)	682.22[f]	--	825.49	1097.39	961.99	1058.19[f]
M.2. ICU (OTHER)	619.70[f]	--	749.84	--	1000.0	--
M.3. CCU	588.48[f]	--	--	783.27	956.44	1052.08[f]
M.4. GENERAL WARD (PRIVATE)	--	--	--	--	299.76	--
M.5. GENERAL WARD (SEMI-PRIVATE)	175.52[f]	--	212.38[f]	233.65	299.76	329.74[f]
M.6. GENERAL WARD (OTHER)	--	--	--	--	--	--
M.7. OTHER	--	--	--	--	--	--

Notes:

a - 1978 unavailable. Used 1979 estimates.
b - 1983 unavailable. Used 1982 estimates.
c - Uses occupational therapy ratio.
d - Uses laboratory ratio.
e - Uses supplies ratio.
f - Extrapolated rate; assumes 10% annual increase.

TABLE 28-A-3
CONVERSION FACTORS FOR MEDICARE COSTS--
MEDICAL COLLEGE OF VIRGINIA

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
A. MEDICAL, SURGICAL, AND CENTRAL SUPPLIES						
A.1. MEDICAL SUPPLIES	--	.7004	.4041	.9358	--	.8880
A.2. SURGICAL SUPPLIES	--	.7004	.4041	.9358	1.0935	.8880
A.3. CENTRAL SUPPLIES	--	3.1529	2.6653	.9358	1.0935	.8880
A.4. OTHER SUPPLIES	--	.7004	.4041	--	1.0935	--
A.5. TOTAL SUPPLIES	--	--	--	--	--	--
B. OPERATING ROOM AND ANESTHESIA						
B.1. OPERATING ROOM	--	1.0541	1.1064	.9521	.9074	.9695
B.2. ANESTHESIA (EXCLUDING PROFESSIONAL TIME)	--	.9978	.9194	1.0905	1.0058	.9043
B.3. OTHER	--	1.0541	1.1064	.9521	--	.9695
B.4. TOTAL OPERATNG ROOM AND ANESTHESIA	--	--	--	--	--	--
C. PHARMACY						
C.1. DRUGS, IN-HOSPITAL	--	.8979	.9082	.8031	.7472	.7083
C.2. DRUGS, TAKE-HOME OR DISCHARGE	--	.8979	.9082	.8031	.7472	.7083
C.3. I.V. SOLUTIONS	--	.8979	.9082	.8031	.7472	.7083
C.4. ALL OTHER DRUGS	--	--	--	--	--	--
C.5. TOTAL PHARMACY	--	--	-	--	--	--
D. THERAPY						
D.1. RESPIRATORY/INHALATION THERAPY	--	.5596	.6490	.6551	.6134	.5584
D.2. VOCATIONAL/OCCUPATIONAL THERAPY	--	1.0917	1.1298	1.1409	.8134	.8408
D.3. PHYSICAL THERAPY/PHYSICAL MEDICINE	--	1.2303	1.050	1.0271	1.0130	1.0728
D.4. OTHER THERAPY	--	--	--	1.1409	--	--
D.5. TOTAL THERAPY	--	--	--	--	--	--
E. APPLIANCES	--	--	--	--	--	--

TABLE 28-A-3 (Continued)
CONVERSION FACTORS FOR MEDICARE COSTS--
MEDICAL COLLEGE OF VIRGINIA

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
F. DIAGNOSTIC TESTS						
F.1. EKG	--	.5516	.5991	.4967	.4681	.4191
F.2. CARDIAC MONITORING/ CARDIAC CATH LAB	--	.9842	1.0650	1.1036	.9211	.8483
F.3 RADIOLOGY (X-RAY)	--	.8905	.7827	.9336	.9284	.9090
F.4 RADIATION MEDICINE	--	--	--	1.1594	1.1440	--
F.5. NUCLEAR MEDICINE	--	1.2939	1.1770	1.1706	1.0293	.8354
F.6 INFECTIOUS DISEASE	--	--	--	--	--	--
F.7 SURGICAL PATHOLOGY	--	--	--	--	.6911	.8489
F.8 OTHER DIAGNOSTIC TESTS	--	.7840	.7203	.7299	.7348	.5642
F.9 TOTAL DIAGNOSTIC TESTS	--	--	--	--	--	--
G. BLOOD ADMINISTRATION						
G.1. BLOOD TRANSFUSION	--	--	.9834	--	--	--
G.2. BLOOD BANK	--	.9205	.9834	.8251	.7348	.6239
G.3. COAGULATION LABORATORY	--	.9205	.9834	.8251	.7348	.6239
G.4. BLOOD PROCESSING	--	--	.9834	--	--	--
G.5. BLOOD PLASMA (PROC)	--	--	--	--	--	--
G.6. BLOOD ADMINISTRATION	--	--	--	--	--	--
G.7. BLOOD LAB	--	--	.9834	--	--	--
G.8. OTHER	--	.9205	--	--	--	--
G.9. TOTAL BLOOD AND ADMINISTRATION	--	--	--	--	--	--
H. OXYGEN AND GAS MIXTURES	--	.5596	.6490	.6551	.6134	.5584

TABLE 28-A-3 (Continued)
CONVERSION FACTORS FOR MEDICARE COSTS--
MEDICAL COLLEGE OF VIRGINIA

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
I. LABORATORY TESTS						
I.1 HEMATOLOGY	--	.7840	.7203	.7299	.7348	.5642
I.2. CHEMISTRY	--	.7840	.7203	.7299	.7348	.5642
I.3. IMMUNOLOGY IMMUNOPATHOLOGY	--	.7840	.7203	.7299	.7348	.5642
I.4. PULMONARY PHYSIOLOGY	--	--	--	--	--	.5642
I.5. VIROLOGY	--	--	--	.7299	--	--
I.6. MICROBIOLOGY	--	.7840	.7203	.7299	.7348	.5642
I.7. DRUG ASSAY	--	.7840	.7203	.7299	.7348	.5642
I.8. CLINICAL LABORATORY TESTS (IF GIVEN)	--	--	--	--	--	--
I.9. PATHOLOGY LAB TESTS (IF GIVEN)	--	.7840	.7203	.7299	.7348	.5642
I.10. ICU LABORATORY TESTS	--	--	--	--	--	--
I.11. OTHER LABORATORY TESTS	--	--	--	--	--	--
I.12. TOTAL LABORATORY TESTS	--	--	--	--	--	--
J. OTHER SERVICES	--	--	.7203[a]	--	.7348[a]	.5642[a]
K. MISCELLANEOUS	--	--	--	.9358[b]	--	--
L. PROFESSIONAL FEES						
L.1. ANESTHESIOLOGY	--	.8000	.8000	.8000	.8000	.8000
L.2. CARDIOLOGY	--	.8000	.8000	.8000	.8000	.8000
L.3. SURGERY	--	--	--	.8000	.8000	.8000
L.4. RADIOLOGY	--	.8000	.8000	.8000	.8000	.8000
L.5. PULMONARY PHYSICIAN	--	--	--	--	.8000	.8000
L.6. OCCUPATIONAL THERAPIST	--	--	--	--	--	.8000
L.7. OTHER	--	--	.8000	.8000	.8000	.8000
L.8. OTHER	--	--	--	.8000	.8000	.8000

TABLE 28-A-3 (Continued)
CONVERSION FACTORS FOR MEDICARE COSTS--
MEDICAL COLLEGE OF VIRGINIA

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
L.9. OTHER	--	--	.8000	.8000	.8000	.8000
L.10. OTHER	--	--	--	--	--	.8000
L.11. TOTAL PROFESSIONAL FEES	--	--	--	--	--	--
M. ROOM AND BOARD (COST PER DAY)						
M.1. ICU (SURGICAL)	--	408.95	461.52	560.85	795.01	696.16
M.2. ICU (OTHER)	--	--	320.53	--	--	588.05
M.3. CCU	--	246.78	279.68	--	408.12	512.91
M.4. GENERAL WARD (PRIVATE)	--	124.03	142.59	146.54	181.57	204.18
M.5. GENERAL WARD (SEMI-PRIVATE)	--	124.03	142.59	146.54	181.57	204.18
M.6. GENERAL WARD (OTHER)	--	--	142.59	--	181.57	204.18
M.7. OTHER	--	--	--	--	181.57	204.18
M.8. TOTAL ROOM AND BOARD	--	--	--	--	--	--

Notes:

a - Uses laboratory ratio.
b - Uses central supplies ratio.

TABLE 28-A-4
CONVERSION FACTORS FOR MEDICARE COSTS--
MINNESOTA

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
A. MEDICAL, SURGICAL, AND CENTRAL SUPPLIES						
A.1. MEDICAL SUPPLIES	.9613	.7410[b]	7281[b]	.6671[b]	.7520	.7520
A.2. SURGICAL SUPPLIES	.9613	.7410[b]	.7281[b]	.6671[b]	.7520	.7520
A.3. CENTRAL SUPPLIES	.9613	.7410[b]	.7281[b]	.6671[b]	.7520	.7520
A.4. OTHER SUPPLIES	--	--	--	--	.7520	.7520
A.5. TOTAL SUPPLIES	--	--	--	--	--	--
B. OPERATING ROOM AND ANESTHESIA						
B.1. OPERATING ROOM	.8051	.8469	.8397	.8752	.7801	.7801
B.2. ANESTHESIA (EXCLUDING PROFESSIONAL TIME)	.8488	.8169	.8119	.8308	1.0190	1.0190
B.3. OTHER	--	.8469	.8397	.8752	.7801	.7801
B.4. TOTAL OPERATING ROOM AND ANESTHESIA	--	--	--	--	--	--
C. PHARMACY						
C.1. DRUGS, IN-HOSPITAL	.8944	.9218	.9494	.8017	.7707	.7707
C.2. DRUGS, TAKE-HOME OR DISCHARGE	.8944	.9218	.9494	.8017	.7707	.7707
C.3. I.V. SOLUTIONS	.8944	.9218	.9494	.8017	.7707	.7707
C.4. ALL OTHER DRUGS	--	--	--	--	.7707	.7707
C.5. TOTAL PHARMACY	--	--	--	--	--	--
D. THERAPY						
D.1. RESPIRATORY/INHALATION THERAPY	.8234	.6185	--	--	.6647	.6647
D.2. VOCATIONAL/OCCUPATIONAL THERAPY	.9508[c]	.9508	1.0316	1.6443	.7520	.7520
D.3. PHYSICAL THERAPY/PHYSICAL MEDICINE	4.7664	3.9576	2.4311	2.2417	1.9181	1.9181
D.4. OTHER THERAPY	--	--	--	--	--	--
D.5. TOTAL THERAPY	--	--	--	--	--	--
E. APPLIANCES	--	--	--	--	--	--

TABLE 28-A-4 (Continued)
CONVERSION FACTORS FOR MEDICARE COSTS--
MINNESOTA

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
F. DIAGNOSTIC TESTS						
F.1. EKG	.8403	.8417	.8244	.8295	.7520	.7520
F.2. CARDIAC MONITORING/ CARDIAC CATH LAB	.8403	.8417	.8244	.8295	.7520	.7520
F.3 RADIOLOGY (X-RAY)	.6774	.6636	.6538	.6238	.6602	.6602
F.4 RADIATION MEDICINE	--	--	--	--	--	--
F.5. NUCLEAR MEDICINE	--	--	--	.6238	.6602	.6602
F.6 INFECTIOUS DISEASE	--	--	--	--	--	--
F.7 SURGICAL PATHOLOGY	--	--	--	--	--	--
F.8 OTHER DIAGNOSTIC TESTS	--	--	--	.6238	.6602	.6602
F.9 TOTAL DIAGNOSTIC TESTS	--	--	--	--	--	--
G. BLOOD ADMINISTRATION						
G.1. BLOOD TRANSFUSION	--	--	--	--	--	--
G.2. BLOOD BANK	--	--	--	--	--	--
G.3. COAGULATION LABORATORY	--	--	--	--	--	--
G.4. BLOOD PROCESSING	--	--	--	--	--	--
G.5. BLOOD PLASMA (PROC)	--	--	--	--	--	--
G.6. BLOOD ADMINISTRATION	1.2778	1.2399	1.3141	.8939	.8636	.8636
G.7. BLOOD LAB	--	--	--	--	--	--
G.8. OTHER	--	--	--	--	--	--
G.9. TOTAL BLOOD AND ADMINISTRATION	--	--	--	--	--	--
H. OXYGEN AND GAS MIXTURES	.8234	.6185	.6288	.7136	.6647	.6647

TABLE 28-A-4 (Continued)
CONVERSION FACTORS FOR MEDICARE COSTS--
MINNESOTA

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
I. LABORATORY TESTS						
I.3 HEMATOLOGY	.7750	.7410	.7281	.6671	.6699	.6699
I.2. CHEMISTRY	.7750	.7410	.7281	.6671	.6699	.6699
I.3. IMMUNOLOGY IMMUNOPATHOLOGY	.7750	.7410	.7281	.6671	.6699	.6699
I.4. PULMONARY PHYSIOLOGY	.7750	.7410	.7281	.6671	.6699	.6699
I.5. VIROLOGY	.7750	.7410	.7281	.6671	.6699	.6699
I.6. MICROBIOLOGY	.7750	.7410	.7281	.6671	.6699	.6699
I.7. DRUG ASSAY	.7750	.7410	.7281	.6671	.6699	.6699
I.8. CLINICAL LABORATORY TESTS (IF GIVEN)	.7750	.7410	.7281	.6671	.6699	.6699
I.9. PATHOLOGY LAB TESTS (IF GIVEN)	.7750	.7410	.7281	.6671	.6699	.6699
I.10. ICU LABORATORY TESTS	--	--	.7281	.6671	.6699	.6699
I.11. OTHER LABORATORY TESTS	.7750	.7410	.7281	.6671	.6699	.6699
I.12. TOTAL LABORATORY TESTS	--	--	--	--	--	--
J. OTHER SERVICES	.7750[b]	.7410[b]	--	.6671	.7520	.7520
K. MISCELLANEOUS	--	--	--	--	.7520	.7520
L. PROFESSIONAL FEES						
L.1. ANESTHESIOLOGY	--	--	--	--	--	--
L.2. CARDIOLOGY	.8000	.8000	.8000	.8000	.8000	.8000
L.3. SURGERY	--	--	--	--	--	--
L.4. RADIOLOGY	--	--	--	--	.8000	.9000
L.5. PULMONARY PHYSICIAN	--	--	--	--	--	--
L.6. OCCUPATIONAL THERAPIST	--	--	--	--	--	--
L.7. OTHER	--	--	.8000	.8000	--	.8000
L.8. OTHER	--	--	--	--	--	--

TABLE 28-A-4 (Continued)
CONVERSION FACTORS FOR MEDICARE COSTS--
MINNESOTA

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
L.9. OTHER	--	--	--	--	--	--
L.10. OTHER	--	--	--	--	--	--
L.11. TOTAL PROFESSIONAL FEES	--	--	--	--	--	--
M. ROOM AND BOARD						
M.1. ICU (SURGICAL)	395.30	439.95	495.84	617.70	780.24	985.55
M.2. ICU (OTHER)	342.33	363.16	411.81	604.51	691.91	791.95
M.3. CCU	353.66	384.53	430.61	512.79	707.05	974.90
M.4. GENERAL WARD (PRIVATE)	155.24	167.50	175.50	165.07	178.86	193.80
M.5. GENERAL WARD (SEMI-PRIVATE)	155.24	167.50	175.50	165.07	178.86	193.80
M.6. GENERAL WARD (OTHER)	--	--	175.50	165.07	178.86	193.80
M.7. OTHER	--	--	--	--	--	--

Notes:

a - Uses FYE 1982 rates with cost per diem extrapolated.
b - Uses laboratory ratio.
c - Uses rate for FYE 1979.

TABLE 28-A-5
CONVERSION FACTORS FOR MEDICARE COSTS--
PITTSBURGH

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
A. MEDICAL, SURGICAL, AND CENTRAL SUPPLIES						
A.1. MEDICAL SUPPLIES	--	--	--	--	--	.5389
A.2. SURGICAL SUPPLIES	--	--	--	--	--	.5389
A.3. CENTRAL SUPPLIES	--	--	--	.6300	1.2318	.5389
A.4. OTHER SUPPLIES	--	--	--	--	1.2318	--
A.5. TOTAL SUPPLIES	--	--	--	--	--	--
B. OPERATING ROOM AND ANESTHESIA						
B.1. OPERATING ROOM	--	--	--	.7754	.7936	.7387
B.2. ANESTHESIA (EXCLUDING PROFESSIONAL TIME)	--	--	--	.7245	.7764	.7286
B.3. OTHER	--	--	--	.7754	.7936	.7387
B.4. TOTAL OPERATING ROOM AND ANESTHESIA	--	--	--	--	--	--
C. PHARMACY						
C.1. DRUGS, IN-HOSPITAL	--	--	--	.7680	.6861	.7417
C.2. DRUGS, TAKE-HOME OR DISCHARGE	--	--	--	--	.6861	--
C.3. I.V. SOLUTIONS	--	--	--	.7680	.6861	.7417
C.4. ALL OTHER DRUGS	--	--	--	--	--	.7417
C.5. TOTAL PHARMACY	--	--	--	--	--	--
D. THERAPY						
D.1. RESPIRATORY/INHALATION THERAPY	--	--	--	.4840	.4582	.4542
D.2. VOCATIONAL/OCCUPATIONAL THERAPY	--	--	--	.6110[a,b]	.6110[b]	.5139[b]
D.3. PHYSICAL THERAPY/PHYSICAL MEDICINE	--	--	--	.6111[a]	.6111	.5139
D.4. OTHER THERAPY	--	--	--	--	-	--
D.5. TOTAL THERAPY	--	--	--	--	--	--
E. APPLIANCES	--	--	--	.6300[c]	1.2318[c]	.5389[c]

TABLE 28-A-5 (Continued)
CONVERSION FACTORS FOR MEDICARE COSTS--
PITTSBURGH

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
F. DIAGNOSTIC TESTS						
F.1. EKG	--	--	--	.4578[a]	.4578	.4007
F.2. CARDIAC MONITORING/ CARDIAC CATH LAB	--	--	--	1.044	.6499	.6049
F.3 RADIOLOGY (X-RAY)	--	--	--	.5060	.4295	.3858
F.4 RADIATION MEDICINE	--	--	--	.8412	.8597	.7110
F.5. NUCLEAR MEDICINE	--	--	--	.5325	--	.4980
F.6 INFECTIOUS DISEASE	--	--	--	--	--	--
F.7 SURGICAL PATHOLOGY	--	--	--	.6980[d]	.6650[d]	.5987[d]
F.8 OTHER DIAGNOSTIC TESTS	--	--	--	--	.6650[d]	.5987[d]
F.9 TOTAL DIAGNOSTIC TESTS	--	--	--	--	--	--
G. BLOOD ADMINISTRATION						
G.1. BLOOD TRANSFUSION	--	--	--	--	--	--
G.2. BLOOD BANK	--	--	--	--	--	--
G.3. COAGULATION LABORATORY	--	--	--	--	--	--
G.4. BLOOD PROCESSING	--	--	--	--	--	--
G.5. BLOOD PLASMA (PROC)	--	--	--	--	--	--
G.6. BLOOD ADMINISTRATION	--	--	--	.8196	.7773	.7612
G.7. BLOOD LAB	--	--	--	.8196	.7773	.7612
G.8. OTHER	--	--	--	--	--	--
G.9. TOTAL BLOOD AND ADMINISTRATION	--	--	--	--	--	--
H. OXYGEN AND GAS MIXTURES	--	--	--	.6980[d]	.6650[d]	.5987[d]

TABLE 28-A-5 (Continued)
CONVERSION FACTORS FOR MEDICARE COSTS--
PITTSBURGH

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
I. LABORATORY TESTS						
I.1 HEMATOLOGY	--	--	--	.6980	.6650	.5987
I.2. CHEMISTRY	--	--	--	.6980	.6650	.5987
I.3. IMMUNOLOGY IMMUNOPATHOLOGY	--	--	--	.6980	.6650	.5987
I.4. PULMONARY PHYSIOLOGY	--	--	--	--	.6650	.5987
I.5. VIROLOGY	--	--	--	--	--	--
I.6. MICROBIOLOGY	--	--	--	.6980	.6650	.5987
I.7. DRUG ASSAY	--	--	--	--	--	--
I.8. CLINICAL LABORATORY TESTS (IF GIVEN)	--	--	--	--	--	--
I.9. PATHOLOGY LAB TESTS (IF GIVEN)	--	--	--	--	--	--
I.10. ICU LABORATORY TESTS	--	--	--	.6980	.6650	.5987
I.11. OTHER LABORATORY TESTS	--	--	--	.6980	.6650	.5987
I.12. TOTAL LABORATORY TESTS	--	--	--	--	--	--
J. OTHER SERVICES	--	--	--	.6980[d]	.6650[d]	.5987[d]
K. MISCELLANEOUS	--	--	--	.6300[c]	1.2318[c]	.5389[c]
L. PROFESSIONAL FEES						
L.1. ANESTHESIOLOGY	--	--	--	--	--	--
L.2. CARDIOLOGY	--	--	--	.8000	--	--
L.3. SURGERY	--	--	--	--	--	--
L.4. RADIOLOGY	--	--	--	.8000	.8000	.8000
L.5. PULMONARY PHYSICIAN	--	--	--	.8000	.8000	8000
L.6. OCCUPATIONAL THERAPIST	--	--	--	--	--	--
L.7. OTHER	--	--	--	--	--	.8000
L.8. OTHER	--	--	--	--	--	--

TABLE 28-A-5 (Continued)
CONVERSION FACTORS FOR MEDICARE COSTS--
PITTSBURGH

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
L.9. OTHER	--	--	--	--	--	--
L.10. OTHER	--	--	--	--	--	--
L.11. TOTAL PROFESSIONAL FEES	--	--	--	--	--	--
M. ROOM AND BOARD (COST PER DAY)						
M.1. ICU (SURGICAL)	--	--	--	682.13	722.59	794.85
M.2. ICU (OTHER)	--	--	--	--	--	794.85
M.3. CCU	--	--	--	312.14	352.24	387.46
M.4. GENERAL WARD (PRIVATE)	--	--	--	148.75	167.59	184.34
M.5. GENERAL WARD (SEMI-PRIVATE)	--	--	--	148.75	167.59	184.34
M.6. GENERAL WARD (OTHER)	--	--	--	--	--	184.34
M.7. OTHER	--	--	--	--	167.59	184.34

Notes:

a - Use 1982 ratio. None given in 1981.
b - Uses physical therapy ratio.
c - Uses supplies ratio.
d - Uses laboratory ratio.

TABLE 28-A-6
CONVERSION FACTORS FOR MEDICARE COSTS--
STANFORD UNIVERSITY

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
A. MEDICAL, SURGICAL, AND CENTRAL SUPPLIES						
A.1. MEDICAL SUPPLIES	--	--	--	--	--	--
A.2. SURGICAL SUPPLIES	.8882	.8351	.7927	.5468	.3716	.4165
A.3. CENTRAL SUPPLIES	.8882	.8351	.7927	.5468	.3716	.4165
A.4. OTHER SUPPLIES	--	--	.7927	--	.3716	--
A.5. TOTAL SUPPLIES	--	--	--	--	--	--
B. OPERATING ROOM AND ANESTHESIA						
B.1. OPERATING ROOM	.9031	.8510	.8889	.8567	.7729	.6724
B.2. ANESTHESIA (EXCLUDING PROFESSIONAL TIME)	1.401	1.397	1.0805	.8436	.7949	.7650
B.3. OTHER	.9031	--	.8889	.8567	.7729	.6724
B.4. TOTAL OPERATING ROOM AND ANESTHESIA	--	--	--	--	--	--
C. PHARMACY						
C.1. DRUGS, IN-HOSPITAL	.6516	.6756	.6646	.8315	.7635	.7668
C.2. DRUGS, TAKE-HOME OR DISCHARGE	--	--	--	--	--	.7668
C.3. I.V. SOLUTIONS	--	--	--	--	--	--
C.4. ALL OTHER DRUGS	--	--	--	--	--	.7668
C.5. TOTAL PHARMACY	--	--	--	--	--	--
D. THERAPY						
D.1. RESPIRATORY/INHALATION THERAPY	.7349	.7641	.7073	.6460	.6473	.6069
D.2. VOCATIONAL/OCCUPATIONAL THERAPY	--	--	--	--	.7496	.8231
D.3. PHYSICAL THERAPY/PHYSICAL MEDICINE	.8728	1.0601	--	1.0158	.9842	.9177
D.4. OTHER THERAPY	--	--	--	--	.9842	--
D.5. TOTAL THERAPY	--	--	--	--	--	--
E. APPLIANCES	.8882[a]	.8351[a]	.7927[a]	.5468[a]	--	--

TABLE 28-A-6 (Continued)
CONVERSION FACTORS FOR MEDICARE COSTS--
STANFORD UNIVERSITY

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
F. DIAGNOSTIC TESTS						
F.1. EKG	.6620	.6665	.6026	.5694	.5675	.5392
F.2. CARDIAC MONITORING/ CARDIAC CATH LAB	1.2530	.8438	.8792	.8785	.9735	.7760
F.3 RADIOLOGY (X-RAY)	1.1512	1.0195	.9475	.8145	.7980	.6999
F.4 RADIATION MEDICINE	--	--	.8722	.9647	.9001	.9074
F.5. NUCLEAR MEDICINE	--	--	1.1254	1.0184	1.0711	.9664
F.6 INFECTIOUS DISEASE	.7300[b]	.7777[b]	.7204[b]	.6344[b]	.5923[b]	.6233[b]
F.7 SURGICAL PATHOLOGY	.7300[b]	.7777[b]	.7204[b]	.6344[b]	.5923[b]	.6233[b]
F.8 OTHER DIAGNOSTIC TESTS	--	.7777[b]	--	--	.5923[b]	.6233[b]
F.9 TOTAL DIAGNOSTIC TESTS	--	--	--	--	--	--
G. BLOOD ADMINISTRATION						
G.1. BLOOD TRANSFUSION	.8475	.9366	.8535	.7622	.7074	.7308
G.2. BLOOD BANK	1.0603	1.0862	1.1188	1.1374	1.0655	1.0962
G.3. COAGULATION LABORATORY	.8475	.9366	.8535	.7622	.7074	.7308
G.4. BLOOD PROCESSING	--	--	--	--	--	--
G.5. BLOOD PLASMA (PROC)	1.0603	1.0862	1.1188	1.1374	1.0655	1.0962
G.6. BLOOD ADMINISTRATION	--	--	--	--	--	--
G.7. BLOOD LAB	--	--	--	--	--	--
G.8. OTHER	--	--	--	.7622	.7074	.7308
G.9. TOTAL BLOOD AND ADMINISTRATION	--	--	--	--	--	--
H. OXYGEN AND GAS MIXTURES	--	--	--	--	--	--

TABLE 28-A-6 (Continued)
CONVERSION FACTORS FOR MEDICARE COSTS--
STANFORD UNIVERSITY

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
I. LABORATORY TESTS						
I.1 HEMATOLOGY	--	.7777	.7204	.6344	.5923	.6233
I.2. CHEMISTRY	--	.7777	.7204	.6344	.5923	.6233
I.3. IMMUNOLOGY IMMUNOPATHOLOGY	--	.7777	--	.6344	.5923	.6233
I.4. PULMONARY PHYSIOLOGY	--	.7777	.7204	.6344	.5923	.6233
I.5. VIROLOGY	--	.7777	.7204	.6344	.5923	.6233
I.6. MICROBIOLOGY	--	--	.7204	--	--	.6233
I.7. DRUG ASSAY	.7300	.7777	.7204	.6344	.5923	.6233
I.8. CLINICAL LABORATORY TESTS (IF GIVEN)	--	--	--	--	--	--
I.9. PATHOLOGY LAB TESTS (IF GIVEN)	--	--	--	.6344	.5923	.6233
I.10. ICU LABORATORY TESTS	--	--	--	.6344	--	--
I.11. OTHER LABORATORY TESTS	--	--	--	.6344	.5923	.6233
I.12. TOTAL LABORATORY TESTS	.7300	--	--	--	--	--
J. OTHER SERVICES	--	.7777[b]	.7204[b]	.6344[b]	.5923[b]	.6233[b]
K. MISCELLANEOUS	.8882[a]	.8351[a]	.7927[a]	.5468[a]	.3716[a]	.4165[a]
L. PROFESSIONAL FEES						
L.1. ANESTHESIOLOGY	--	--	--	--	--	--
L.2. CARDIOLOGY	--	--	--	--	--	--
L.3. SURGERY	--	--	--	--	--	--
L.4. RADIOLOGY	--	.8000	.8000	.8000	--	--
L.5. PULMONARY PHYSICIAN	--	--	.8000	--	--	--
L.6. OCCUPATIONAL THERAPIST	--	--	--	--	--	--
L.7. OTHER	.8000	8000	.8000	.8000	.8000	.8000
L.8. OTHER	--	--	.8000	.8000	.8000	.8000

TABLE 28-A-6 (Continued)
CONVERSION FACTORS FOR MEDICARE COSTS--
STANFORD UNIVERSITY

COST CATEGORY	FISCAL YEAR (ending in) 1978	1979	1980	1981	1982	1983
L.9. OTHER	--	--	.8000	.8000	--	--
L.10. OTHER	--	--	--	--	--	--
L.11. TOTAL PROFESSIONAL FEES	--	--	--	--	--	--
M. ROOM AND BOARD (COST PER DAY)						
M.1. ICU (SURGICAL)	585.81	670.91	708.04	843.58	936.34	1054.24
M.2. ICU (OTHER)	573.92	606.33	616.68	779.46	--	1020.55
M.3. CCU	424.61	535.47	542.50	643.80	721.90	843.14
M.4. GENERAL WARD (PRIVATE)	159.45	180.28	196.97	235.24	259.12	252.96
M.5. GENERAL WARD (SEMI-PRIVATE)	159.45	180.28	196.97	235.24	259.12	252.96
M.6. GENERAL WARD (OTHER)	159.45	180.28	196.97	235.24	259.12	252.96
M.7. OTHER	159.45	--	--	--	259.12	252.96

Notes:

a - Uses supplies ratio.
b - Uses laboratory ratio.

At the very best, these must be considered an approximation to what factors would have been applied at the time had the patients been covered under Medicare. In practice, it was impossible ex post to link accurately the Medicare Cost Report's cost centers with those used in these six hospitals. Both the billing systems and Medicare report format changed frequently over the years within the hospitals though this is more a problem for ancillary cost centers than for routine stays or intensive care. Note that conversion factors are presented only where they were needed for the calculation. That is, if a center had no patients on a given year or use in a particular category, no conversion factor was developed. Also, note that in instances where data were missing or the linkage unclear, some approximating assumption was made. These assumptions, admittedly, crude in some cases, are listed in the notes to each table. In general, however, this probably has little impact on the overall cost-effectiveness or cost projections.

APPENDIX 28-B

NATIONAL HEART TRANSPLANTATION STUDY
PHYSICIAN SERVICES QUESTIONNAIRE FOR HEART TRANSPLANTATION

Appendix 28-B

NATIONAL HEART TRANSPLANTATION STUDY
PHYSICIAN SERVICES QUESTIONNAIRE FOR HEART TRANSPLANTATION

INTRODUCTION

In estimating the costs of heart transplantation, reimbursement for the physician services provided is perhaps the most difficult component to obtain. The difficulty arises for several reasons: (1) physician bills are not part of the hospital records and are therefore hard to obtain; (2) many different physicians may provide services during a given patient's stay; (3) physician services for heart transplantation have often been donated or covered under a general research grant rather than separately itemized.

In order to fill this gap in our knowledge of the costs of transplantation, we ask your assistance in answering the following questions. We have tried to keep the questions short and logically structured. Feel free, however, to record the same information by some other scheme if it is more applicable to your institution.

At the end of each section we also request the name and telephone number of a person to contact for further information.

Thank you.

I. Surgical Services and Fees

a. Please list the Current Procedural Terminology (CPT-4) or Relative Value Scale Codes (if available) for the surgical services provided to the typical heart transplant recipient or candidate at your institution. (If billing is by a surgical team, please use the appropriate CPT modifier (-66) or make a note. Or if the assistant surgeon bills separately, use the appropriate modifier (-80). Also, be sure to list any services besides the transplant procedure itself, that are billed separately. And, finally, for the post-discharge period list those services that are provided when the patient returns for an annual check-up. In addition, to the code and name of the service, please list the usual fee or charge for the procedure and the frequency (per day, per week, or per stay).

CPT-4 No.	TYPE OF SERVICE OR PROCEDURE	USUAL FEE	FREQUENCY
Initial Evaluation			
Candidacy Period:			
Transplant Period (Transplant thru Discharge):			
Post-Discharge Period:			

b. We assume that the above procedures include normal, uncomplicated follow-up care. Please comment on whether this is true and what is normally involved in this care. For example, how many encounters per day when the patient is in intensive care versus when in a general ward?

c. What is the usual surgeon's fee at your institution for a triple coronary artery bypass (CPT-4 No. 33518)?

$_____

d. Person to contact at your institution for any questions about your response:

Name: _____ Telephone: _____

2. Cardiologist Services and Fees

Please list the usual services or procedures provided by cardiologists to heart transplant candidates and recipients at your institution. If items are provided periodically, please note the frequency (e.g., 3 visits per 7 days).

CPT-4 No.	TYPE OF SERVICE	USUAL FEE	FREQUENCY
Initial Evaluation			
Candidacy Period:			
Transplant Period (Transplant thru Discharge):			
Routine Follow-Up Care:			

Contact if questions: Name: _____ Telephone: _____

3. Anesthesiologist Services and Fees

Please list the usual services or procedures provided by anesthesiologists to heart transplant candidates and recipients at your institution. In addition, to the code and name of the service, please list the usual fee or charge for the procedure and the frequency (per day, per week, or per stay).

CPT-4 No.	TYPE OF SERVICE OR PROCEDURE	USUAL FEE	FREQUENCY

Contact if questions: Name: _____ Telephone: _____

4. Services and Fees of All Other Physician Providers.

If other physician providers bill separately for professional services to heart transplant candidates or recipients at your institution, please list those types of physicians and services. In addition, to the code and name of the service, please list the usual fee or charge for the procedure and the frequency (per day, per week, or per stay).

CPT-4 No.	TYPE OF SERVICE/PROCEDURE	USUAL FEE	FREQUENCY
Physician Type: _____			
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
Physician Type: _____			
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
Physician Type: _____			
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
Physician Type: _____			
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Contact if questions: Name:_____ Telephone:_____

5. Miscellaneous Services and Fees

Are there other charges (by physicians or others) not in the hospital billing records that should be included?

COMMENT: _____

Thank you.

CHAPTER 29

THE COST-EFFECTIVENESS OF HEART TRANSPLANTATION

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A. INTRODUCTION

This chapter combines the parameter estimates on the medical costs related to the heart transplantation with estimates of patient survival from the NHTS (see Chapters 20, 21 and 22). The primary objective is to examine the cost-effectiveness (CE) of heart transplantation from HCFA's point of view, but some attention is given to its CE from a broader societal perspective as well.

The second section presents the conceptual framework. There is first a general introduction to CEA, followed by a presentation of the specific model used here. Section C presents the parameter estimates used and discusses the results. Section D compares the CE of heart transplantation with that of several other technologies, including kidney dialysis and kidney transplantation. The final section summarizes the findings and discusses the limitations of the analyses.

B. CONCEPTUAL FRAMEWORK

1. COST-EFFECTIVENESS ANALYSIS: SOME GENERAL ISSUES

In recent years several authors have written introductions to cost-benefit analyses (CBA) and cost-effectiveness analysis (CEA) applications in medical care and medical technology (see, for example, Weinstein and Stason, 1977, and Shepard and Thompson 1979). There have also been several reviews and critiques of these procedures as they are applied (see, for example, Dunlop, 1975, and Gaspari, 1983). The basic difference between CBA and CEA as applied in program evaluation is that the former attempts to quantify all aspects of a program change in dollar terms, while the latter leaves some program

effects unvalued, expressed in qualitative terms such as incremental years of survival or enhanced quality of life. CEA finesses the difficult issues of valuing life, reductions in pain, etc., but at a severe cost in terms of its generalizability.

CEA, if used to guide resource allocation decisions, is of necessity a relative concept. A given program cannot be absolutely cost-effective: it can be only cost-effective relative to some alternative. The usual examples given comparing two programs A and B are: (1) when both programs have the same effect or outcome, such as saving ten lives, the cost-effective program is the one which costs least, or (2) if both programs cost the same, the cost-effective program is the one saving a greater number of lives.

In practice, the program alternatives are often at best implicit. For instance, after HCFA has the cost-effectiveness ratio of heart transplantation in hand, with which alternative use of Medicare dollars should it be compared? Or, even, with which alternative use of taxpayer dollars should it be compared? In fact, it is generally misleading to speak of "the" cost-effectiveness ratio of a given program. Cost-effectiveness usually varies with the size of the program or the population served. In economic jargon, most programs are not constant returns to scale: their effects and/or average costs depend on the size of the program. Furthermore, the costs and effects of a health program depend on patient characteristics. What is cost effective for one person may not be cost effective for another.

2. MODEL

The cost-effectiveness of heart transplantation (HT) from HCFA's point of view can be represented by the following ratio:

$$\text{Cost-Effectiveness} = \frac{\text{Change in Expected Costs}}{\text{Change in Expected Life Years}}$$

$$= \frac{\begin{array}{c}\text{(Expected Costs with HT Coverage} \\ \text{- Expected Costs without HT Coverage)}\end{array}}{\begin{array}{c}\text{(Expected Survival with HT Coverage} \\ \text{- Expected Survival without HT Coverage)}\end{array}}$$

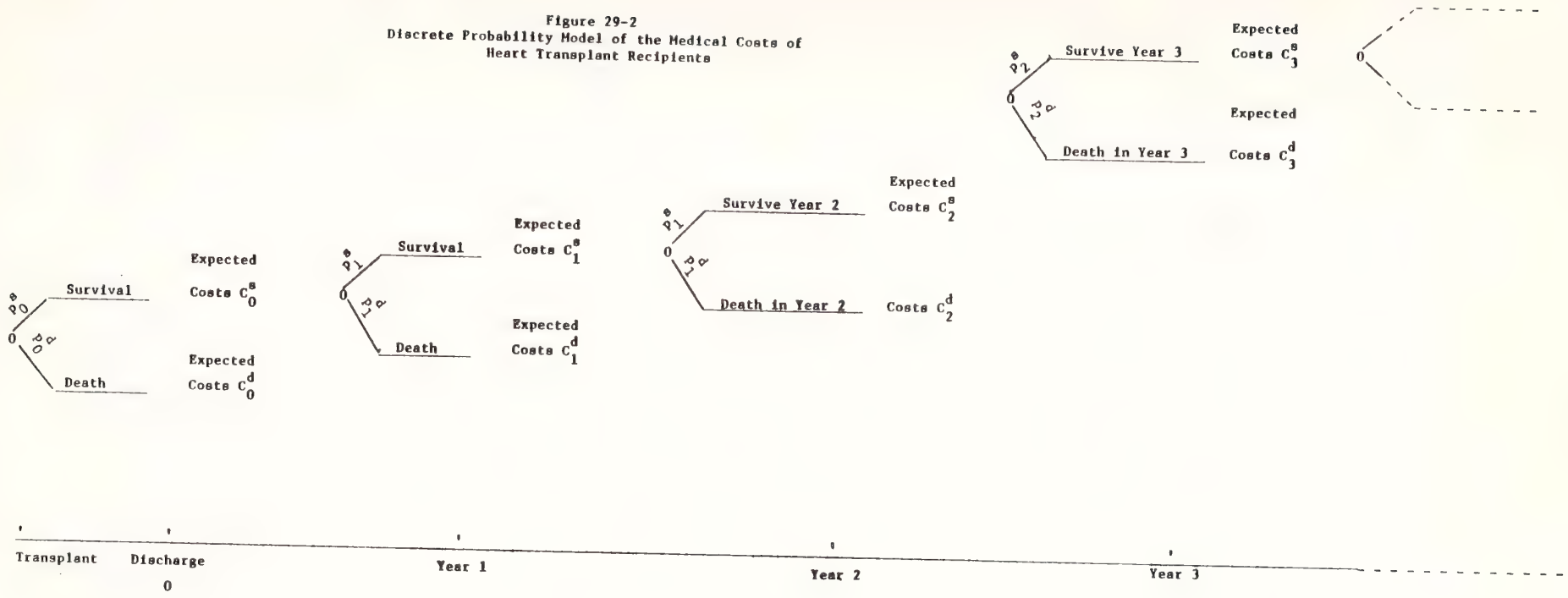
Figure 29-1 shows how each of the elements of this ratio is calculated. The underlying model is a simple discrete model with discounting. The elements are expressed in present value terms. Period 0 includes the evaluation, candidacy, and transplant periods. Periods 1 through n are all post-discharge years. Figure 29-2 shows how the expected costs for heart transplantation can be depicted as a probability tree with each branch representing a particular event (survival or death) during a particular interval. For example, p_3^s is the conditional probability of surviving through the third year post-transplant; $p_3^d (=1-p_3^s)$ is the conditional probability of dying during the third year. (Note that Figure 29-1 contains joint probabilities which are the products of the conditional probabilities; for example, $p_2^s = p_0^s \cdot p_1^s \cdot p_2^s$).

The expected costs without heart transplant are the product of expected additional survival (in months) without a heart transplant (M) and average costs per month C_M during this period. The former is estimated using survival data on those who died awaiting transplant,

Figure 29-1
Elements of the Cost-Effectiveness Ratio for Heart Transplantation

Element	Formula
Expected Costs with Heart Transplant	$= \sum_{i=0}^{n} \frac{(P_i^s C^s{}_i P_i^d C_i^d}{(1+r)^i}$
Expected Costs without Heart Transplant	$= M \cdot C$ where C_M = cost per month during candidacy
Expected Costs with Heart Transplant	$= \sum_{i=1}^{n} \frac{(P_i^s + .5 P_i^d}{(1+r)^i}$
Expected Additional Survival without Heart Transplant	$= M$

Figure 29-2
Discrete Probability Model of the Medical Costs of
Heart Transplant Recipients



and the latter estimation, using candidacy costs prior to transplantation, was described in Chapter 28.

Expected survival with heart transplant is the present value of the stream of survival years. The conditional probabilities in Figure 29-2 are multiplied to yield p^s_i, the probability of surviving period i, and p^d_i, the probability of dying in period i. The conditional probabilities are estimated based on the experience at the six centers.

3. COST PERSPECTIVES

As stated at the beginning of this chapter, this CEA takes HCFA's perspective primarily. It is important to understand how this differs from other perspectives--social or private--and what assumptions about HCFA's coverage are made.

The major difference between taking this perspective versus another is in regard to costs. First, if cost-shifting from the Medicare to the non-Medicare population is prevalent, then the costs to HCFA will understate the costs to society. Second, since the patient pays some share via coinsurance and deductibles, HCFA's share of social costs are further reduced. Third, HCFA's costs in years post-transplant include routine medical expenditures (e.g., care for accidental injuries) that may be unrelated to the transplant. A proper societal cost-effectiveness analysis would not count these. Including them obviously raises the total costs of the procedure, thereby raising its cost-effectiveness ratio. Note that analyses of the ESRD Program have typically included these unrelated expenses.

It is certainly possible that other parameters in the model, such as the number evaluated per eventual recipient or the survival rates, could differ between the Medicare and non-Medicare populations. This, too, could give rise to differences between HCFA's and society's CE ratios. However, the model as estimated here does not differentiate these parameter values for the two populations.

One unique issue for CE from HCFA's perspective concerns the termination of Medicare benefits. For example, if transplants are restricted to those under 55, then the Medicare transplant recipients are largely those eligible for coverage because of long-term disability. This disability status depends on the ability to "engage in substantial gainful activity." If the transplant recipients become healthy enough to return to work, then Medicare benefits will be terminated. Should there be some postulated termination date in this model? It would seem so, unless the program were to be set up like the ESRD Program. Successful kidney transplantation under the ESRD Program eventually results (after 3 years) in the termination of Medicare coverage. One alternative would be to assume a similar cutoff date for heart transplantation. This analysis does not deal explicitly with this issue, but instead assumes lifetime coverage (similar to kidney dialysis). Under current coverage provisions, this causes some overstatement of costs to HCFA, but because the largest expenditures are incurred initially, with discounting the impact may be small. This approach has the advantage of yielding cost estimates closer to social costs.

Results from the NHTS Living Recipient Survey showed that 31.6 percent were working. (Their average survival time was 3.0 years.) On the other hand, up to 51 percent claimed to be too ill to work. What this implies for the termination of benefits is unclear, but it is important to recognize that the CE of heart transplantation from HCFA's point of view will depend on the legal provisions related to coverage.

This discussion also raises the issue of one of the important indirect costs of transplantation--disability payments--from the federal government. They may not be a cost to HCFA, but they are a cost to taxpayers and are sometimes viewed as a cost to society. The NHTS Survey of Living Recipients indicated that 62.5 were receiving federal income support via Social Security Disability or Retirement Benefits. This analysis of medical cost-effectiveness does not include these disability payments. They are not costs to HCFA, and their status as costs to society is debatable since they can be viewed as payments under a social insurance scheme.

C. PARAMETER ESTIMATES AND RESULTS

Tables 29-1 and 29-2 present the underlying parameter estimates used in the CE analysis done from HCFA's point of view. The first table presents the final medical costs estimates, whose estimation was described in the preceding chapter. The second table presents the rates and probabilities needed in the model. The estimates in Table 29-2 are largely drawn from other portions of the NHTS and receive more detailed discussion in the remainder of this section.

Table 29-1[a]
Summary of Parameter Estimates for
Medical Costs to HCFA

Phase and Element	Base Case	Range	
		Low	High
I. PRE-TRANSPLANT			
A. Evaluation Cost	$ 3,700	$2,700	$5,200
B. Candidacy Cost (per month)	$ 6,151	$1,000	--
II. TRANSPLANT PERIOD COSTS			
A. Survivors	$75,085	$60,843	$88,675
B. Dececents	$80,286	$67,230	$98,502
III. POST-DISCHARGE ANNUAL COSTS			
A. First Year:			
- Survivors	$ 9,535	--	$14,016
- Decedents	$11,810	--	$17,684
B. Second Year and Beyond:			
- Survivors	$ 6,261	--	$ 7,975
- Decedents	$ 8,911	--	$12,750

[a]This is identical to Table 28-18.

Table 29-2
Summary of Rates and Probability
Parameter Estimates

Rate or Probability	Estimates		
	Base Case	Low	High
Number of Medicare patients evaluated per candidate	1.5	1.3	4.0
Mean length of candidacy prior to transplant (days)	35	--	--
Number of Medicare candidates per recipient	1.2	1.15	2.0
Mean length of alternative survival post-transplant (months)	3.0	1.7	9.0
Conditional Survival Probability:			
Transplant period	.80	.75	.85
One year	.70	.60	.75
Two years	.90	.85	.94
Three years	.90	.85	.94
Four years	.90	.85	.94
Five years	.90	.85	.94
Six years	.95	.90	.97
Seven years	.95	.90	.97
Eight years	.95	.90	.97
Nine years	.95	.90	.97
Ten years	.95	.90	.97
Eleven to nineteen years	.98	.98	.98
Discount rate (%)	6.0	2.5	10.0

1. RATE AND PROBABILITY ESTIMATES

a. Pre-Transplant Phase. The model presented above includes the parts of the pre-transplant phase--evaluation and candidacy--in period 0. It is easy to overlook the fact that for any one transplant that is performed for a Medicare beneficiary, many beneficiaries may have gone through evaluation, and several through candidacy. Heart transplantation is going to be more expensive to the extent screening (i.e. evaluation) for potential candidates is a costly activity. And screening can be costly because either many must be screened or because each evaluation is costly. Since the objective of this chapter is to project the cost-effectiveness per transplant, some assumptions must be made about the number evaluated and the number declared candidates in order to yield one eventual transplant.

The NHTS attempted to document the historical experience of the six programs in this regard. Programs were asked to report the number evaluated and of those the number declared candidates. The difficulty with applying this to a larger population is, again, that these centers, because of size limitations, may have been more selective in their declaration of candidates than might be the case in the future.

The reported experience (Baumgartner et al., 1979) at Stanford and the data collected in the NHTS provide an historical basis for projecting the number of evaluations and the number of candidates declared per eventual recipient. Although in principle all of those in need (as well as others) could be evaluated, this is unlikely given institutional constraints and other realities. And

even if they were all evaluated, it is not obvious that the number declared candidates would be based strictly on medical criteria. There might be an element of first-come first-serve. Since heart transplant programs must ration a scarce supply of hearts and of staff time, they will have an incentive to maintain a waiting list that is organizationally manageable.

For this reason it may be better to argue backward from the number of expected transplants to the number evaluated and declared candidates. Baumgartner et al. (1979), reporting on one years' referrals indicate that of 168 referrals (appropriate by an age criterion), 27.4 percent were brought to Stanford for full evaluation, and 50 percent of those were declared candidates. At the time of the analysis, 60.9 percent of the candidates had received a transplant, and 26.1 percent were awaiting a transplant. The remainder had died. Reversing the sequence would imply approximately 1.25 candidates per eventual recipient, and 2 evaluations per declared candidate. These figures are shown in column one of Table 29-3. This assumes that programs work backward from the expected volume of procedures, which depends on what they are willing to do (given staff and facility constraints) and able to do (given the availability of donor organs).

The results from the NHTS are shown in the second column in the top panel of Table 29-3. For the period under study, 418 transplants have been done at the six centers. It is estimated that 700 full evaluations were performed at the centers, and that between 471 and 496 persons were declared candidates (the responses were unclear in some cases). Estimation is, of course, complicated by the

Table 29-3
Evaluation and Candidacy Parameters

I. BACKGROUND DATA

	Stanford Experience For One Year[a]	NHTS
Evaluations per Candidate	2	1.41 - 1.49
Candidates per Recipient	1.25	1.13 - 1.19

II. ASSUMPTIONS

	Base Case	Low	High
Evaluations per Candidate	1.5	1.3	4.0
Candidates per Recipient	1.20	1.15	2.0

[a]As reported in Baumgartner et al. (1979).

fact that five candidates were alive and awaiting a transplant. In developing a base case assumption for the future, the historical experience at the six centers is viewed as being at the low end because of the experimental nature of the procedure.

The assumed parameter estimates are shown in Table 29-3. The Stanford estimates, coming from an experimental program are best regarded as low estimates. The base case estimate is that 1.2 candidates are declared per recipient and 1.5 evaluations performed per candidate. A high estimate might well be for all those in need to be evaluated. The implied ratio of evaluations to eventual recipient would then be on the order of 40, instead of 1.8 as in the base case. Eschewing this as unrealistically high, the assumed high estimates are 2 candidates per recipient and 4 evaluations per candidate. It should be obvious that 8 evaluations per eventual recipient could significantly increase the cost of transplantation as compared with 1.8, as assumed in the base case.

b. Alternative Survival. Two of the most important parameters in estimating the cost-effectiveness of heart transplantation are survival and expenses in the absence of the transplant. Would the recipients have died at home at little expense? Or would they have been hospitalized in an ICU in the local community accumulating a large expense in the process of dying? The difficulty of answering these counterfactual questions should be obvious. If transplant recipients would have died costly deaths at local hospitals, then the net costs of heart transplantation may be small.

The data generated in the NHTS provide some scope, limited though it is, for addressing these questions. As described in Chapter 28, the approach here is to separate the costs of dying into a time element--expected net survival without a transplant--and a cost element--costs incurred per unit time during that period. For example, if the mean survival without the transplant is three months (from the day of the operation), then the cost avoided is three times the cost per month in the last months of life.

The expected survival was to come from the survival analyses, but unfortunately because of delays in data collection and preparation those analyses are not complete. The cost per month estimates were described in Chapter 28. For now, it is necessary to make some ad hoc assumptions for alternative survival. Two pieces of evidence from the NHTS are that (1) recipients have a mean candidacy period of 35 days, and (2) those candidates who die awaiting transplant have a mean candidacy of 45 days. Since it is believed that programs try to give organs to those most ill at any point, the former piece of evidence, as well as the latter suggest that expected survival may not be long. Sophisticated statistical analyses of the early Stanford experience (see Aitkin, Laird, and Francis, 1983) have found expected survival with transplantation to be much longer than without, but the difference is questionable because of the great variability in the estimates.

Because of the need to complete these analyses, it is necessary to make some first-cut assumptions with regard to expected survival. These are shown in Table 29-2. First, the base case

estimate is for 3 months, which implies an alternative cost of $18,453. The low estimate is 1.7 months: this was set as equal to the mean length of stay of recipients--of 52 days. The high estimate is 9 months. Refinement of these must await the completion of further survival analyses.

c. Survival Probabilities. Table 29-4 shows the derivation of the survival probabilities summarized in Table 29-2. The top panel is based on an interpolation of the probabilities predicted using a Cox model for white recipients, as reported in the NHTS survival analyses. The second panel is based on the unadjusted experience of the centers in the study, excluding those currently living in a particular post-discharge year. This could result in biased estimates.

The probability of being discharged alive falls between .75 and .85. The first year post-discharge appears to be a crucial period: probabilities of surviving that period vary between .59 and .75. In later years, the probability of surviving is higher, fluctuating between .8 and .95. The small number of observations after seven years makes projection past that point a matter of substantial conjecture. A reasonable assumption is that the living recipients have close to the same survival probabilities as the general population of the same age.

Note that Stanford's performance is improving over time, and the other centers, as a group, appear to lag somewhat behind. Of course, analysis of this issue would require some case-mix adjustment, as is done in the chapters on survival.

Table 29-4
Derivation of Survival Probability Parameters[a]

I. Interpolated Conditional Probabilities from Cox Model for Whites

Period										
0	1	2	3	4	5	6	7	8	9	10
.841	.747	.860	.926	.798	.867	.949	.968	--	--	--

II. Simple Conditional Survival Probabilities (Number of observations in parentheses)

Sample	Period										
	0	1	2	3	4	5	6	7	8	9	10
All centers, all years	.732 (418)	.594 (212)	.898 (98)	.873 (71)	.873 (52)	.846 (31)	.936 (24)	.824 (17)	1.0 (10)	1.0 (7)	1.0 (5)
1973-80, Stanford	.752	.635	.944	.882	.825	.957	.882	.800	1.0		
Post-1980, Stanford	.852	.750	.937	.750	--						
Other Five	.699	.477	.857	--							

III. Assumed Parameter Values

	Period										
	0	1	2	3	4	5	6	7	8	9	10
Base Case	.80	.70	.90	.90	.90	.90	.95	.95	.95	.95	.95
Low	.75	.60	.85	.85	.85	.85	.90	.90	.90	.90	.90
High	.85	.75	.94	.94	.94	.94	.97	.97	.97	.97	.97

[a]On this page, period 0 represents the time from day of transplant to discharge.

The probabilities assumed for the base case are not mathematically derived from the estimates in the top panels. There are rough, subjective estimates, balancing apparent trends intuitively. At some point, it would be preferable to substitute estimated probabilities from a Cox model based on post-discharge experience.

The base case projects survival at five years post-discharge to be 36.7 percent of those transplanted. The low survival probabilities imply 23.5 percent survival five years post-discharge, and the high values 49.8 percent. Although this table shows only 10 years of probabilities, the cost-effectiveness computations used a 20-year horizon to be sure not to understate expected survival significantly. For example, since with the high probabilities, 10-year survival would be over 40 percent, a 10-year horizon (i.e. assuming all die by the tenth year) would significantly reduce predicted mean life expectancy. A 20-year horizon lessens this problem. The yearly conditional probability for years 11 to 19 is assumed to be .98. This was chosen based on a life table for the U.S. males in 1982 (U.S. Bureau of Census, 1984). The conditional survival probability was .982 for a male beginning his sixtieth year. Thus, a rate only slightly below this was chosen.

This underscores another source of uncertainty in cost-effectiveness analysis: life expectancy depends importantly on the time horizon chosen, given the rates used here for the first ten years. For example, without discounting or netting out alternative survival, the 10-year horizon implies a mean life expectancy of 4.0

years; a 20-year horizon 6.6 years. On the other hand, discounting the 20-year horizon at 6 percent yields a life expectancy of 4.2 years. Given the lack of experience with patients after 10 years post-discharge, this cost-effectiveness analysis contains by necessity a large degree of uncertainty.

d. Discounting. Because resources today can be invested to yield greater returns in the future, projected benefits and costs in the future must be discounted in present value terms. The controversy surrounding the appropriate discount rate is well-known. The problem arises in part because of differences between the social rate of time preference and the opportunity cost of funds used for public investment. In the design of the NHTS, HCFA required the use of alternative discount rates. Following the suggested practice in Hodgson and Meiners (1982), three discount rates are used: 2.5%, 6%, and 10%. They argue that the social rate of time preference is the more relevant criterion in this case, and that the rates of 2.5 and 6 percent contain this rate. However, they suggest using all three. Note that the formulas used here tend to overdiscount a bit since period 0 (including evaluation, candidacy, and transplant) is typically less than a year.

Weinstein and Stason (1977) have argued persuasively that future effects as well as future costs should be discounted in the same sense that future benefits would be discounted. Thus, the formula for life expectancy in Figure 29-1 contains a discount factor; undiscounted life expectancy is reported as well.

2. COST-EFFECTIVENESS RESULTS

Table 29-5 presents the base case results in the top panel. The cost per life year gained is $23,478. The total net costs are $96,237 in present value terms, which represents costs above the alternative cost of $18,453. Discounted expected survival time is 4.1 years; the undiscounted expected survival is 6.5 years. Survival at five years post-discharge is 36.7 percent. In other words, $96,237 in 1983 dollars would buy 4.1 years of discounted life expectancy.

The second panel in Table 29-5 shows the sensitivity of the results to alternative assumptions about (1) the discount rate and (2) alternative survival. Estimated cost per life year gained varies between $14,000 and $30,000. Cost per life year rises with the discount rate because most costs are incurred early on. Increased alternative survival lowers net costs; these costs are also incurred early on, so the effect does not vary much by the discount rate.

It may be somewhat surprising that moving from three month to nine month alternative survival only reduces the cost (at 6.0 percent discount) of a life year gained from $23,478 to $16,486. Nine month alternative survival implies an alternative cost of $55,359. But it also reduces expected net survival by one-half year. Evidence presented in Chapter 28 suggests that this alternative cost is on the high side. The cost of $18,453 may be a better estimate, even if 9 months might be preferred as the alternative survival.

The estimate of alternative survival is both important and uncertain. What if it were longer? Under the base case, an alternative survival of 12 months (but keeping alternative cost at

Table 29-5
Cost-Effectiveness Results
(Expressed in Cost per Life Year Gained)

I. Base Case Results (20-year Time Horizon; Discount Rate = 6.0)[a]

Period	Expected Cost	Survival Probability
0	$76,125	.800
1	8,152	.560
2	3,674	.504
3	3,306	.454
4	2,976	.408
5	2,678	.367
6	2,362	.349
7	2,244	.332
8	2,132	.315
9	2,026	.299
10	1,924	.284

Alternative Cost = $18,453

Cost per Life Year Gained = $23,478 ($96,237/4.099 years)

II. Sensitivity Results (Cost per Life Year Gained in 1983 dollars)

	Discount Rate (%)		
Alternative Survival	2.5	6.0	10.0
1.7 months	$21,467	$25,445	$30,258
3.0 months	$19,811	23,478	28,002
9.0 months	$14,152	16,486	19,574

[a]Conditional survival probability in years 11-19 is .98.

$18,453) would reduce cost-effectiveness--from $23,478 to $28,736 per life year gained; 18 month alternative survival would raise the cost per life year gained to $33,779.

As the model is currently formulated, there are no additional costs for more candidates other than initial evaluation costs. After evaluation, candidates who die awaiting a transplant, are assumed to impose no additional costs on HCFA: their costs of dying would have been borne in any case. Thus, the parameter of 1.2 candidates per recipient is ignored. Of course, a case can be made that candidates are likely to receive more life-extending care (this may underlie the $6,151 candidacy cost per month). If there are such costs, they would diminish the cost-effectiveness of heart transplantation.

D. COMPARISON WITH OTHER TECHNOLOGIES

This section reports the CE of other technologies. First, ESRD treatment with an emphasis on kidney transplantation is discussed at length. This is particularly relevant since it represents an alternative use of funds from HCFA's point of view. Second, results from studies on coronary bypass surgery and other technologies are discussed.

1. COST-EFFECTIVENESS OF KIDNEY TRANSPLANTATION

a. Cost Studies. The numerous studies on the cost-effectiveness of alternative modalities for ESRD have perhaps paid more attention to the issue of home versus in-center hemodialysis treatment than dialysis versus transplantation. The emphasis may be shifting because of a growing belief in the cost-effectiveness of

transplantation as well as a substantial decline in the proportion of patients on home treatment.

Table 29-6 summarizes the results from previous studies. The studies shown represent both cost studies and cost-effectiveness analyses. The table shows first the costs assumed (i.e., baseline costs) for the various modalities or related events, and the survival probabilities assumed. These assumptions or parameter estimates are inputs into the cost-effectiveness analysis. The right-hand column shows the results of these studies in terms of cost per life year gained where reported. These figures are the outputs of the cost-effectiveness analyses. Costs per year of treatment or life year gained are on the order of $10,000 - $20,000. Five year recipient survival ranges from 60 to 90 percent for kidney transplants.

Although these studies generally support the view that kidney transplantation is cost-effective relative to dialysis, it is difficult to compare any two studies because of differences in underlying assumptions. Practically speaking, the comparison is difficult because published reports seldom provide a complete description of the study.

Several recent analyses (Eggers, 1983; Krakauer et al., 1983; Roberts et al., 1983) of the ESRD Program in the U.S. have relied on estimates produced by Dr. Paul Eggers at HCFA using the information collected in the Medicare Statistical System. Table 29-7 reproduces the key underlying estimates being used.

Even casual examination of these data is revealing. First, the program cost data alone do not unambiguously establish the

Table 29-6

A Summary of Studies on the Cost-Effectiveness of ESRD Treatment

STUDY	OBJECTIVE	COST DATA	SURVIVAL DATA	RESULTS
1. Klarman et al. (1968)	To compare the relative cost-effectiveness of center dialysis, home dialysis, and kidney transplatation.	Source: Gottschalk Committee, U.S. data Estimate: (1967 Dollars) Center: $14,000/year; Home: $5,000/year; Transplant: $13,000/procedure	Source: Gottschalk Committee, U.S. data Estimates: (by dialysis versus transplant) Dialysis--55.7% survival at 5 years Transplant--54.4% survival at 5 years	Cost per live year gained Center: $11,600/year Home: $4,200/year Transplant: $2,600/year $2,200/year (quality-adjusted)
2. Comptroller General (1975)	To compare cost-effectiveness of center versus home dialysis.	NOT APPLICABLE	Source: European Dialysis and Transplant Association through 1972.	Source: Estimates: (1972 Dollars) Center: $27,600/year Home: first year $4,900 later years $7,000
3. Buxton and West (1975)	To compare cost-effectiveness of hospital versus home dialysis.	Source: Two centers in Great Britain Estimates: (1972) prices Hospital: $13,720/year; Home: $6,615/year	Source: European Dialysis and Transplant Association through 1972 Estimates: Hospital--53% at 5 years Home--67 1% at 5 years	Cost per life year saved. Hospital: $11,564 Home $6,370 (discount rate: 10%)
4. Hoffstein et al. (1976)	To estimate and compare cost per dialysis for home, home training, limited care, satellite, and hospital.	Source: Five major dialysis centers in U.S. Estimates: (1973) prices Gathered detailed expenditure data for several categories	NOT APPLICABLE	Annual Cost: Self-care, home $6,729 Full-care, center $16,520 Full-care, hospital $24,738 Also estimates per session costs for self-care training
5. Warner and Kolff (1976)	To compare the costs of home versus center dialysis	Source: Microcosting using input prices and Medicare charges Estimates: (1975 Dollars)	NOT APPLICABLE	Annual costs Center dialysis $23,400 Home dialysis First year w o technician $12,898 First year w technician $17,728 Succeeding year w o technician: $10,044 Succeeding year w technician $15,504

Table 29-6 (Continued)

A Summary of Studies on the Cost-Effectiveness of ESRD Treatment (cont.)

STUDY	OBJECTIVE	COST DATA	SURVIVAL DATA	RESULTS
6. Stange and Sumner (1978)	To compare the cost-effectiveness of facility dialysis, home dialysis, and cadaveric transplantation.	Source: Internal Management Reports of HCFA Estimates: (1976 Dollars) Center Dialysis: First Year: $17,000 Succeeding years: $15,400 Cadaveric Transplant: First year: $25,000 Succeeding years: $3,000, $2,000, $1,500, $1,500, etc. or $9,000 if unstable. Costs of rejecting: $10,000	Source: National Dialysis Registry Human Renal Transplant Registry (both U.S. data) Estimates: (as of 1976) Center: 61.6% at 5 years Home: 63.7% at 5 years Cadaveric Transplant: Patient: (51.0-60.0%) at 5 years Graft: (34.6-36.0%) at 5 years	Cost per life year saved: Center: $26,550 Home: $16,987 Cadaveric: $15,007 $15,472 (Cost estimates were discounted at 5 percent of life years at 7 percent)
7. Plonski (1978)	To compare costs between home and facility dialysis.	Source: Estimates: Home: First year: $21,300 Succeeding years: $11,800 Center: $20,700	NOT APPLICABLE	
8. Blagg (1978)	To discuss ESRD treatment in general and provide figures on treatment at the Northwest Kidney Center.	Source: Northwest Kidney Center Estimates: (1977 Dollars)	Source: Northwest Kidney Center All dialysis patients: 58% at 3 years Home Patients: 74% at 3 years	Annual Costs: Home dialysis: $11,566-$15,436 Center Medicare reimbursement $23,400 (Does not include hospitalization costs)
9. Pearson et al. (1976)	To estimate and compare costs of home versus center dialysis prior to Federal funding	Source: Estimates: 12 facilities in Connecticut Home: Gottschalk Committee	NOT APPLICABLE	Center dialysis: $14,000 - $15,000 Home: $5,610 per year (claimed 9 of 12 centers losing money)

Table 29-6 (Continued)

A Summary of Studies on the Cost-Effectiveness of ESRD Treatment (cont.)

STUDY	OBJECTIVE	COST DATA	SURVIVAL DATA	RESULTS
10. Schippers and Kalff (1976)	To estimate and compare costs of center hemodialysis versus transplantation.	Source: Estimates: (1973 Dollars) Center-Dutch health insurance companies Transplant-two Dutch hospitals	NOT APPLICABLE	Center dialysis: $26,000 per year Renal transplant. First year $18,000 Second year $3,200 w/functioning graft
11. Hampers and Hager (1977)	To compare home versus center dialysis, using examples of Northwest and Boston Kidney Centers.	Source: Boston Kidney Center Northwest Kidney Center as reported to Congress	NOT APPLICABLE	Home dialysis: Boston: w/partner: $18,635 per year w/o partner: $23,624 per year
12. Roberts et al. (1980)	To compare cost-effectiveness of four ESRD treatment modalities.	Source: U.S. Federal Government Home dialysis: First year: $22,760 Succeeding years: $13,237 Center dialysis: $24,800/year LRD transplant: First year: $20,700 Second year: $1,500 Succeeding years: $500 CAD transplant: First year: $23,400 Second year: $3,000 Third year: $1,500 Succeeding years: $750 Graft rejection Death: $9,000	Source: U.S. data from reports to National Dialysis Registry and Human Renal Transplant Registry. Use age-specific rates (e.g., three years survival for those 31-45): Home dialysis: 64.4% LDR transplant: 72.2% CAD transplant: 49.2%	Cost per life year gained Center dialysis: $24,800 Home dialysis: $13,274 Cadaveric Transplant: $14,918 Living-related Transplant: $7,709

Table 29-6 (Continued)

A Summary of Studies on the Cost-Effectiveness of ESRD Treatment (cont.)

STUDY	OBJECTIVE	COST DATA	SURVIVAL DATA	RESULTS
13 Ludbrock (1981)	To compare cost-effectiveness of hospital dialysis, home dialysis and transplantation.	Source: British Department of Health and Social Security Prices: (1976-77 British pounds) Exchange rate--$1.80.1/ pound Estimates available from author	Source: Graft and patient survival (by age groups) from European Dialysis and Transplant Association Dialysis-to-transplant transition from NE Thomas Regional Health Authority Probabilities available from author. Estimates: (by dialysis versus transplant)	Cost per life year gained Hospital dialysis: $12,816-$10,216 Home dialysis: $9,296-$10,469 Transplantation: $5,866-$8,363 Ends of range based on high/low assumption of costs. Assume 7% discount rate.
14 Kraukauer et al. (1983)	To project program cost-effectiveness and total costs to HCFA under varying assumptions.	Source: HCFA reimbursement records Estimate: (1979 Dollars) Dialysis--Maintenance $18,179/year Entry: $1,025/year Death: $5,432/per year Transplantation-- Procedure: $16,273/year Maintenance, functioning graft: $4,074/year Return to Dialysis: $11,956 Death: $15,161	Source: Dialysis patients from HCFA; Transplant survival from the Kidney Transplantation Histocompatibility Study Dialysis paient 5 years survival 33.4% Transplant patient survival: (not given explicity in article)	General finding. HCFA ESRD Program total costs and enrollment over the next eight years are insensitive to likely increased rates of transplantation due to cyclosporine, etc.
15 Eggers (1983)	To estimate program cost-effectiveness of renal transplantation.	Source: HCFA reimbursement records Estimates: (1979 Dollars)	Source. HCFA patient survival experience Estimates:	Finding. Renal transplantation is more cost-effective from HCFA s point of view. Average cost per year over five years Dialysis $18 800 Transplant: $15 800

Table 29-6 (Continued)

A Summary of Studies on the Cost-Effectiveness of ESRD Treatment (cont.)

STUDY	OBJECTIVE	COST DATA	SURVIVAL DATA	RESULTS
16. Belzer et al. (1982)	To report costs and survival for renal transplantation at one center by type of donor (cadaveric vs. living-related) and by type of recipient (diabetic vs. non-diabetic).	Source: University of Wisconsin Transplant Services, last 7 years Hospital costs: transplant (for rest of year): Cadaveric: Diabetic: $15,317 ($7,561) Nondiabetic: $12,717 ($4,683) Living Related: Diabetic: $12,633 ($4,104) Nondiabetic: $11,125 ($1,967)	Source: University of Wisconsin Transplant Data Patient survival at 5 years Cadaveric: Diabetic: 70% Nondiabetic: 88% Living Related: Diabetic: 82% Nondiabetic: 96%	- Living-related more cost-effective (over one year) than cadaveric - Diabetic less cost-effective than nondiabetic.
17. Roberts et al. (1983)	To compare cost-effectiveness of ESRD treatment modalities from HCFA's and society's point of view.	Source: HCFA Reimbursement Records for 1979 Center Dialysis: $23,343/year Home Dialysis-Equipment: $15,400 Supplies: $17,399 Training: $3,034 Transplant surgery: $20,400 Cadaveric Transplant Followup: First year $6,000 Second year $4,800 Third year $2,900 LRD Transplant Followup: First year $4,800 Second year $2,400 Third year $1,200 Graft rejection: $12,600 Transplant Death: $9,000	Source: HCFA-ESRD-MIS records Rates are age-specific; Example: 30-45 yr old, five year survival: Dialysis 50.3% Transplant: LRD: 91.8% CAD: 80.3%	Costs per life year: Center dialysis: HCFA: $23,300 Society: $29,200 Home dialysis: HCFA: $18,800 Society: $24,100 Cadaveric transplant: HCFA: $12,600 Society: $16,800 LRD transplant: HCFA: $5,700 Society: $8,300
18. Salvateirra et al. (1979)	To analyze costs and outcomes for 466 patients at one center.	Source: Hospital costs for transplant patients at UCSF for 1972-1976	Source: UCSF 466 patients from 1972-76	Costs: First year LRD transplants: $14,658 Cadaveric transplant: $16,574 Second year Functioning Graft LRD transplant: $185 Cadaveric transplant: $1,120 Survival (1 year) LRD: 100% CAD: 90%

Table 29-7
Kidney Transplantation Parameters

I. SURVIVAL BY MODALITY (Percent Surviving)

Year	Dialysis	Living Related Transplant		Cadaveric Transplant	
		Graft	Recipient	Graft	Recipient
1	86	75	91	51	83
2	73	71	89	46	77
3	64	67	86	41	72
4	58	63	82	35	66
5	52	60	81	31	59

II. AVERAGE MEDICARE ANNUAL REIMBURSEMENT BY PATIENT OUTCOME, 1979

Outcome	Medicare Reimbursement per Person Year
Transplant - 1st year - Graft Functioning	$32,067
Transplant - 1st Year - Graft Failed	44,639
Transplant - 1st Year - Death	62,886
Transplant - 2nd Year - Graft Functioning	4,074
Transplant - 2nd Year - Graft Failed	30,189
Maintenance Dialysis	18,127
Death on Dialysis	28,253

SOURCE: Eggers (1983); Tables 1, 2, 3.

superiority of transplantation. Transplantation costs are more in the first year than maintenance dialysis, and more per year in later years if the graft fails and/or the patient dies. Transplantation costs are, however, substantially less in the case of a functioning graft. Second, the survival data, especially for the more prevalent cadaveric transplants, do not obviously show that transplantation is more cost-effective. Patient survival at five years for dialysis is 52 percent and for recipients of cadaveric organs is 59 percent (graft survival is only 31 percent). In fact, as Eggers says:

> The results of this analysis show that transplantation in general is more cost-effective treatment for ESRD patients than dialysis, although the net savings do not appear until four years after transplantation. However, given the direction of the trend in costs, each additional year beyond five years will continue to increase the cost-effectiveness of transplantation.

It is important to recognize that this particular cost-effectiveness analysis took HCFA's perspective on costs (i.e., program costs), and did not show the costs to society. (This assumes therefore that the costs to Medicare of transplant recipients with functioning grafts after the third year are zero.) Another HCFA-funded study (Roberts et al., 1983), using these same 1979 reimbursement data, inflated the cost estimates by 25 percent to reflect the difference between Medicare's and society's costs. In neither case have the costs of outpatient drugs, which are not covered under Medicare, been included in the calculation. These have been estimated to be on the order of $2,000 per year under conventional immunosuppression. Of course, a switch to cyclosporine at a cost of $8-11,000 per year would greatly

affect the cost-effectiveness of transplantation, from the patient's point of view if not from Medicare's.

It would probably strike many as surprising that the five-year survival rates shown in Table 29-7 are as low as they are. For those recipients not receiving living-related donor organs, only 50 to 60 percent of patients are alive at five years, and only a third of these cadaveric grafts are still functioning at five years. Clearly, the substantial extra costs associated with patient death and graft failure are an important component of the total costs of ESRD treatment via transplantation. Data limitations may bias the results of the many published cost-effectiveness analyses in the literature. Both survival and cost data are based on historical experience, which reflects an element of self-selection. Unfortunately, detailed data for specific demographic subgroups are usually not available. As Eggers (1983) says:

> It should not be assumed from this analysis that transplantation is always the best option for any ESRD patient. One major constraining factor is age. Very few patients are transplanted over the age of 55, yet 47 percent of all ESRD patients are 55 years or over...

The literature has simply not incorporated the necessary data to reflect significant patient heterogeneity. This omission is important because the relative cost-effectiveness of a treatment is a function of patient characteristics.

Another general limitation of this literature for social decision-making is the reliance on program cost data rather than economic cost data. One exception is home dialysis, where costs have

often been estimated from a description of the resources involved (see Hampers and Hager, 1979, for example). It is easy to understand HCFA's concern with program costs rather than economic costs, the opportunity cost of resources used. Indeed, accurate projections of program costs are essential for government planning. Analysts have often been careful to use program costs to Medicare which differ from charges for hospital services, both because of the patient's deductible and coinsurance payments and because of Medicare's cost-reimbursement principles. Finkler (1982), however, has persuasively shown that neither hospital charges nor Medicare hospital costs are closely-related to economic costs. Furthermore, Bovbjerg et al. (1982) have argued as well that dialysis payments have functioned essentially as charges, and may or may not reflect true economic costs. In other words, the many previous studies which have relied primarily on these charge data, provide at best an approximation of the true economic costs.

All of this is not to say that economic costs are necessarily understated. Under the reimbursement system existing prior to Medicare prospective pricing, hospitals had an incentive to shift (if feasible) accounting costs (especially overhead costs) to cost centers with patients being treated on a cost-reimbursement basis. But at the same time, non-Medicare patients were effectively charged a greater amount for the same itemized services received by a Medicare patient. The net result of this cost shifting has not been reliably estimated and the controversy about who bears the burden will probably continue. However, prospective payment brings with it a new set of incentives

that will affect not only the total costs of treatment but also who bears them.

b. Implications for Heart Transplantation. In comparing these results (particularly those estimates in Table 29-7) several things are noteworthy:

1. Kidney transplant costs in the first year are lower than heart transplant costs: on the order of $75,000-80,000 (in 1983 dollars) for heart transplant versus $30,000-60,000 (in 1979 dollars) for kidney transplant.

2. Graft survival is comparable at five years, but kidney recipient survival is much better (because of dialysis).

3. Costs on dialysis in later years are higher than a survivor's maintenance costs with transplant.

It is also interesting to note that first-year death costs are very high for kidney transplant patients. This makes one wonder why first-year death costs for heart transplant are as low as they are. The possibility that the estimates are biased deserves further investigation.

2. COST-EFFECTIVENESS OF BYPASS SURGERY AND OTHER TECHNOLOGIES

To place the cost effectiveness of heart transplantation in a broader social context, it is useful to compare it with the cost effectiveness estimated for other medical technologies. This section reports briefly on several studies of other technologies. The comparison is never as precise as one would like. The various studies use different discount rates, different approaches to estimating costs, and different methods of estimating effects, such as survival.

Nonetheless, it is instructive to make these comparisons, recognizing their limitations.

Pliskin et al. (1981) estimated the cost effectiveness of coronary artery bypass graft surgery for fourteen hypothetical patients, but relying upon realistic estimates of cost and probabilities of survival. They assume the average cost of the bypass operation to be $15,000, in 1979 prices. They were comparing surgical intervention with conventional medical treatment. Their results were as follows:

> Cost effectiveness calculations indicate that for patients in whom the operation is preferred, costs range from $1,500 to $32,000 per year of quality adjusted life gained...A similar analysis of treatment for essential hypertension indicated costs of between $10,000 and $20,000 per quality adjusted life year gained...

They argue by this comparison that bypass graft surgery appears to be "as reasonable as blood pressure control is for patients with hypertension." Most of the hypothetical patients fell below $10,000 per adjusted life year gained. Thus, even with inflation from 1979 to 1983, bypass surgery is probably favorable as compared with heart transplantation. At the same time, heart transplantation may not be that unfavorable, as compared with treatment for hypertension.

Weinstein (1980) estimated the cost effectiveness of estrogen use by post-menopausal women. Such use is believed to provide relief of menopausal symptoms and prevention of osteoperosis, but at the same time, increasing the risk of cancer and uterine bleeding. Again, the cost effectiveness varied with the characteristics of those receiving treatment. For example, treatment was relatively cost effective in

women with a prior hysterectomy. The ratio was most favorable for symptomatic patients and osteoporotic patients with costs per quality-adjusted life year gained being less than $5,000. Among asymptomatic patients, the cost effectiveness ratio was between $20,000 and $25,000 (in 1980 dollars). Thus, this expenditure of societal resources for symptomatic and osteoporotic would appear to be preferred to heart transplantation.

Boyle et al. (1983) examined the cost effectiveness of neonatal intensive care. They find a cost effectiveness of $2,800 (1978 U.S. dollars) per quality-adjusted life year gained for newborns weighing 1000 to 1499 grams; the cost effectiveness for those weighing 500 to 999 grams was $18,000 per quality adjusted life year gained. Interestingly, when costs are compared with projected future earnings, these analysts report that: "for both birth weight groups, the provision of neonatal intensive care resulted in an increase in costs that was greater than the increase in projected earnings." This analysis of heart transplantation has avoided placing an explicit value on life. However, it should be recognized that a life year gained at age 50 may be valued differently than a life year gained at age 1. Overlooking this caveat would suggest that neonatal intensive care is a relatively cost effective expenditure of society's resources, as compared with heart transplantation.

Willems et al. (1980) studied the cost effectiveness of vaccination against pneumococcal pneumonia. They found that: "...vaccination could add a year of healthy life among all age groups for about $4,800 in net medical care costs." The cost effectiveness

varied greatly depending on the age of the person being vaccinated. Vaccinating those over 65 was much more cost effective than vaccinating those between, say, the ages 2 and 4. It was pointed out that these results had particular relevance to the Medicare program, which did not at the time cover most immunizations and other preventive services. (After the study, these vaccinations became covered expenses.) Of course, as compared with heart transplantation this would appear to be an exceptionally cost effective expenditure of Medicare funds.

The purpose of citing these, admittedly, selective studies is not to stack the deck against heart transplantation. Rather, the objective is to provide the reader with some points for comparison. There are undoubtedly numerous technologies and activities undertaken by our society that have higher cost-effectiveness ratios than heart transplantation.

3. OVERVIEW OF COMPARISONS

Heart transplantation appears to be less cost effective than several technologies, such as bypass surgery, that have been subjected to detailed analysis. The studies that have been conducted in the literature, of course, tend to be those about which there is some controversy. On this score, the cost of gaining a life year via heart transplantation appeared to average more than the cost for these controversial technologies. On the other hand, to the extent comparison is possible, heart transplantation is not vastly inferior, in terms of cost effectiveness, to kidney transplantation and kidney dialysis. Once again, in all of these comparisons it cannot be

overemphasized that cost effectiveness depends upon patient characteristics. For example, the population now receiving kidney transplantation and dialysis differs greatly from the group envisioned to receive this treatment initially.

E. CONCLUSION: SUMMARY AND LIMITATIONS

This chapter combined the medical costs estimates of Chapter 28 with information on survival and screening procedures from other portions of the NHTS. On average recipients were projected to have an undiscounted net life expectancy of 6.5 years. The discounted (at 6%) present value of net costs in the base case was $96,237. When survival is similarly discounted, cost per life year gained is $23,478. This cost-effectiveness ratio was sensitive to reasonable assumptions about (1) discount rates, (2) costs of alternative therapy, and (3) survival probabilities. The ratios from sensitivity analyses fell in the range of $14,000 to $30,000 per life year gained.

Compared with the cost-effectiveness ratios of other medical technologies that have been evaluated, heart transplantation appears to fall at the high end of costs. On the other hand, when compared specifically with kidney transplantation, it does not seem to be clearly more expensive per recipient from HCFA's point of view.

Some important limitations deserve reiteration. First, the assumed values for alternative survival remain based on intuition and on some biased mean values. It is important to revise them once the analysis of nonrecipients in the NHTS is complete. Also, the survival probabilities of recipients should be revised once the analysis is

complete. It would be informative to see how cost-effectiveness varies with personal characteristics as they affect the probability of survival.

Second, it should be remembered that this analysis takes HCFA's perspective. On the one hand, HCFA's costs are probably less than social costs because of cost-shifting and cost-sharing with patients. On the other hand, no adjustment was made for return to work leading to the loss of Medicare benefits--this would tend to raise costs from HCFA's, but not society's, perspective. Furthermore, costs in years post-discharge are not corrected for expenses unrelated to heart transplantation.

Third, although costs of immunosuppresive and other drugs for transplant recipients were estimated in Chapter 28, they are not included in the costs to HCFA used in this chapter. Historically, they have been a minor cost element, running about $1,100 per year, but now cyclosporine is approved and being charged for. If its costs are $8,000 to $11,000 a year as some project, then the cost-effectiveness of heart transplantation to society, if not HCFA, would be reduced substantially.

Finally, this analysis has made no adjustment for the quality of life of recipients although the NHTS has described their quality of life in other chapters. It seems clear that recipients must experience a substantial gain in the quality of life on average if only because the life of someone with end-stage cardiac disease is so miserable. On the other hand, by some absolute standard, the quality of life of recipients may fall below their expectations. Many of them

suffer death shortly after transplantation. This imposes additional psychic costs on them and their families. While the notion of quality-adjusted life years gained has some intuitive appeal, it has not been attempted here because of measurement difficulties. Those considering the cost-effectiveness of heart transplantation must mentally integrate the results in this chapter with those on quality of life in other chapters of the NHTS.

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CHAPTER 30

PROJECTING THE AGGREGATE COSTS OF HEART TRANSPLANTATION: MODEL AND RESULTS

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A. INTRODUCTION

The purpose of this chapter is to project aggregate costs to HCFA for five years (assumed to be 1985-9) after a coverage decision. The model used to make the projection and the assumptions made are described in detail. The projection requires information from all other components of the study: need, survival, organ procurement, psychosocial, legal, and ethical. The historical cost data described in Chapter 28 and the survival probabilities from Chapter 29 serve as the basis for these cost projections.

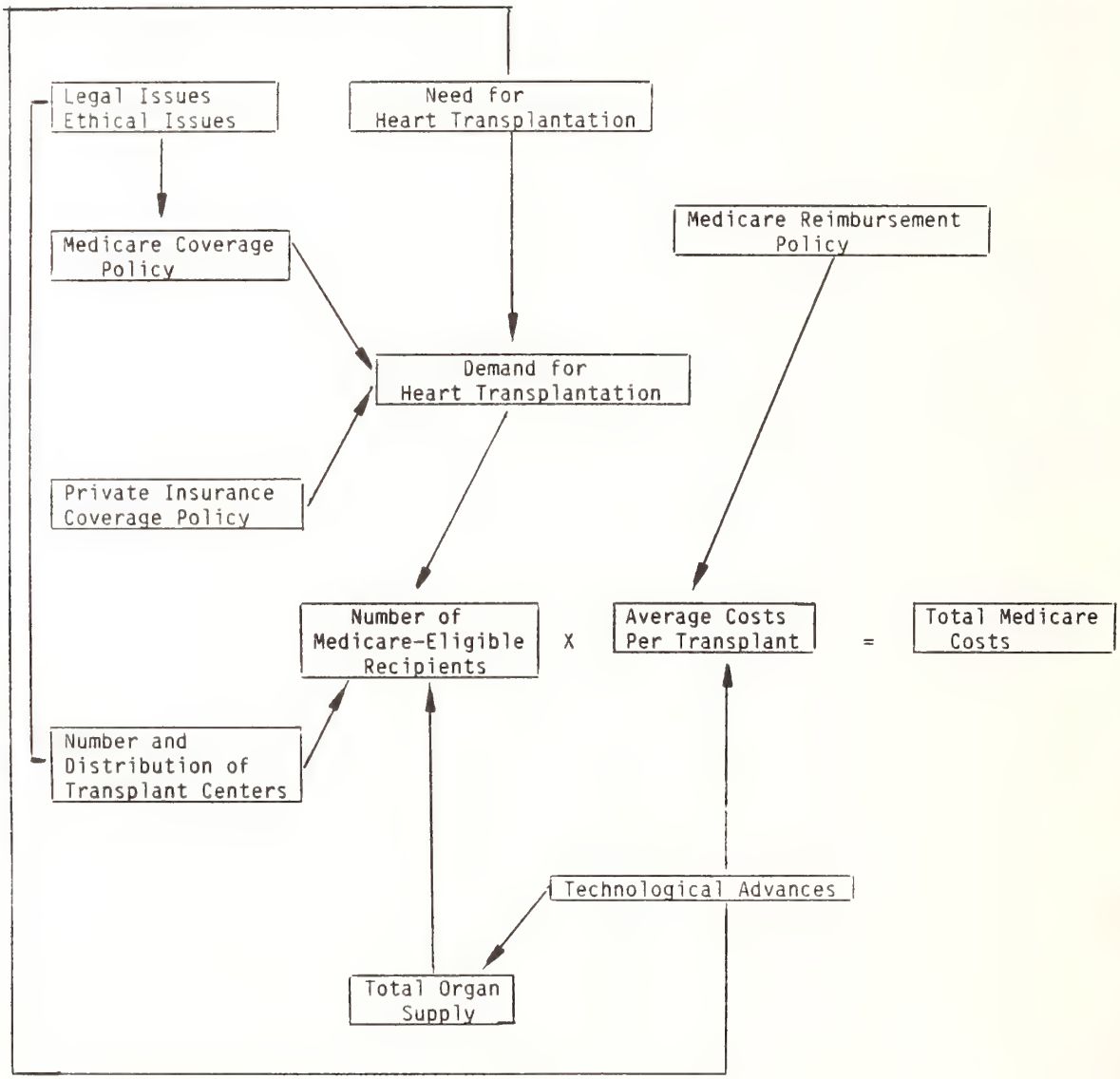
B. MODEL

Figure 30-1 shows how the components of the study are interrelated for the purpose of making this projection. The major factors affecting the costs to Medicare for heart transplantation are the following:

- The need for heart transplantation.
- The demand for heart transplantation.
- The supply of organs.
- The number and distribution of transplant centers.
- Insurance coverage policy and provisions, by Medicare and by private carriers.
- Technological advances.
- Legal and ethical considerations.

Need, a biomedical concept, reflects the prevalence in the population of heart disease for which heart transplantation is considered a therapeutic remedy. The extent to which people who need a transplant in this sense actually seek one is called the "demand" for

Figure 30-1
Factors Affecting Medicare Transplant Costs



transplantation. Demand depends on many factors besides need, including insurance coverage policy and provisions, the preferences of those in need, family income, and the accessibility of transplant centers. (It should be noted in passing that "demand" can include some who might fail a medical need criterion.) Legal and ethical issues are important in many ways, most notably in the development of patient selection criterion and perhaps in the methods used to allocate the scarce supply of hearts.

As is argued below, the availability of organs appears to be an effective constraint on the number of transplants that can be done. Since demand is likely to outstrip the supply of organs, with or without Medicare coverage, it is unclear how the scarce supply will be allocated among those eligible for Medicare and others. In any case, these several factors will determine the number of transplants done in a given period and the number of recipients who are Medicare-eligible. Given the average net cost per transplant to HCFA, it is simply a matter of multiplication to determine total costs to Medicare. Of course, to project costs over a period of years, as is done in this chapter, it is necessary to follow the annual cohort of Medicare transplants over time, taking account of survival.

C. BASE CASE ESTIMATES AND ASSUMPTIONS

To project the costs to HCFA it is necessary to bring together all the components of the study. This section describes the base case estimates for each component and discusses factors to be considered in performing sensitivity analyses.

1. THE NEED FOR TRANSPLANTATION

The need estimates developed in the NHTS were summarized in Chapter 14, Table 14-1. The actual number of current Medicare beneficiaries who might benefit from a heart transplant is difficult to estimate with any precision. The need estimates based on mortality data have more face validity than those based on the morbidity at hospital discharge. Direct mortality data on Medicare beneficiaries was unavailable so an indirect method was used. In 1980, at most 14,085 U.S. citizens would have satisfied the 10-54 age criterion, not all of whom would meet other criteria. It was estimated that approximately 1,000 of these deaths were Medicare beneficiaries.

As has been mentioned many times, a major constraining factor at this point is the scarce supply of donor hearts. Although the available supply of hearts might exceed the number of current Medicare beneficiaries in need, it is unlikely to exceed the total number of hearts needed. Under current eligibility rules, this implies that some of these Medicare beneficiaries would receive a heart while others would not. If Medicare were to adopt a provision similar to the coverage of kidney transplantation, then many more--virtually all of the 14,085--would be covered, and need would vastly outstrip supply.

For the base case analysis, it is assumed that (1) current coverage provisions apply, (2) Medicare beneficiaries in need of a transplant are as likely to receive a heart as others in need, and (3) age 10-54 is the relevant age criterion. Extrapolating the 1980 rates in Table 14-1 to the 1985 population yields the need estimates shown in Table 30-1.

Table 30-1
The Need for Heart Transplantation

I. NHTS RESULTS[a]

	U.S. POPULATION	MEDICARE BENEFICIARIES
1980 Total	14,085	1,020
Per 100,000 U.S. Population age 10-54	9.5827	.6940

II. NEED PROJECTION[b]

YEAR	U.S. POPULATION	MEDICARE BENEFICIARIES
1985	14,640	1,060
1986	14,737	1,067
1987	14,855	1,076
1988	14,970	1,084
1989	15,101	1,094

[a]Based on Table 14-1, uses ICDA-9-CM, age criterion of 10-54, mortality data, and ratio of mortality to morbidity for the U.S. population.

[b]Applies rates from Panel I to U.S. population age 10-54 projected for 1985-89. No other adjustment was made for demographic factors.

The base case estimate is that 1060 Medicare beneficiaries will need a transplant in 1985. An estimate range is not provided since the supply of organs is an effective constraint. These estimates play a part in the model only through the allocation of the scarce supply of hearts to Medicare beneficiaries versus others. Indeed, a constant factor--that Medicare beneficiaries are 7.24% of all those in need--is assumed through 1989 in the base case.

2. ORGAN SUPPLY AND PROCUREMENT

The methods and estimates of the organ supply for the NHTS were described in Chapters 17, 18, and 19. The figures presented there suggest that although the number of potential heart donors could be as many as 16,000 annually, the actual number likely to be available in the near future will be less than 1,000.

For the period 1979-81 it was found that there were approximately 16,000 in-hospital deaths of medically suitable donors per year. Extrapolating to an estimated 1985 population of 238,631,000 implies 16,800 potential donors. However, this total could be reduced because of unwillingness to donate. In Chapter 17, it was reported that only 52.8 percent of the general U.S. population would be willing to donate the organs of relatives who had just died. 25.4 percent were unwilling and 21.8 percent were unsure. On these grounds, at least 8870 donor hearts would be available and at most 12,533 (74.6 percent x 16,800). Of course, this extrapolation makes some strong assumptions about the characteristics and actual response of the families of potential donors.

These figures represent what can be considered a medical and social upper bound. In practice, they are much too optimistic for the period 1985- 89. After all, in Chapter 19 it was estimated that there were only 1846 kidney donors in 1982. Furthermore, only 15-40 percent of those were judged as suitable heart donors. This would seem to be the most reliable basis for projecting the supply of organs in the near term. Nonetheless, some would question its validity. The number of medically suitable kidney donors among in-hospital deaths has been estimated to be between 20,000 and 40,000 per year (Bart et al., 1981; Etheredge et al., 1979). Either the procurement system is very inefficient, other technical considerations make retrieval difficult, or these estimates are in error. Of course, each of these could be a factor. On balance, it seems reasonable to work from existing procurement levels for projections over the next five years.

Table 30-2 presents the background data used to project the number of transplants through 1989. It is unlikely that either the kidney or heart procurement systems will improve dramatically in the near term. Furthermore, donor heart preservation and procurement face more stringent time constraints than kidney procurement. For these reasons, as shown in Table 30-2, the following analysis assumes a low of 250 transplants in 1985, a base case estimate of 400, and a high estimate of 1000. Each figure is arbitrarily assumed to grow at 10 percent per annum, a modest rate that is not inconsistent with the kidney procurement experience. The importance of these projections for total costs should be obvious. The fact that they are, at best, educated guesses should not be forgotten.

Table 30-2
Potential Organ Supply and Expected Procurement

I. NHTS RESULTS

A. Based on In-hospital Deaths[a]

	Maximum Available Per Year	Conditioned on Willingness to Donate
1979-81 Total	16,000	8,448 - 11,936

B. Based on Kidney Procurement[b]

Year	Cadaveric Kidney Donors	Number Suitable as Heart Donors
1980	1711	257-684
1981	1713	257-685
1982	1846	277-738

C. Number of Heart Transplants[c]

Year	Number of Heart Transplants
1979	32
1980	36
1981	62
1982	103
1983	172

II. PROJECTED HEART PROCUREMENT: 1985-89[d]

Year	Base Case	Low	High
1985	400	250	1000
1986	440	275	1100
1987	484	303	1210
1988	532	333	1331
1989	586	366	1464

[a]Derived from results reported in Chapter 18.

[b]From Table 19-8.

[c]From Table 3-4

[d]All recipients, Medicare or not. This is a subjective projection based on the numbers in Panel I. A 10 percent annual growth rate is assumed after 1985.

An additional factor with a potential impact on the volume of procedures is the number and distribution of transplant centers. Results from the NHTS Survey of Open Heart Surgery Facilities, as reported in Chapter 39, suggest that a large number of institutions--over 100--appear to be on the verge of starting heart transplant programs. While this would significantly increase access to the procedure, it would be difficult to justify on efficiency grounds if the supply of hearts is as scarce as projected here. Indeed, it seems unlikely that this much expansion would occur with so few hearts available. Having 100 different programs perform the 400 transplants in 1985 would probably have adverse impacts on costs and survival.

3. EVALUATION AND CANDIDACY

The derivation of estimates of the numbers of persons evaluated and declared candidates per eventual recipient was described in Chapter 29. The base case assumes 1.5 evaluations per candidate and 1.2 candidates per recipient. This implies 1.8 evaluations per eventual recipient. These parameter values are shown in Table 30-3 along with low and high estimates. The low estimates yield 1.5 evaluations per recipient, and the high 8.0 evaluations per recipient. As was discussed in Chapter 29, because of the particular cost assumptions made about candidacy, the ratio of candidates to recipients has no direct role in total program costs.

4. SURVIVAL PROBABILITIES

The derivation of survival probabilities was described in Chapter 29. It bears repeating that the assumed base case parameter values are a subjective extension of the estimated historical

Table 30-3[a]
Summary of Rates and Probability
Parameter Estimates

Rate or Probability	Estimates		
	Base Case	Low	High
Number of Medicare patients evaluated per candidate	1.5	1.3	4.0
Mean length of candidacy prior to transplant (days)	35	--	--
Number of Medicare candidates per recipient	1.2	1.15	2.0
Mean length of alternative survival post-transplant (months)	3.0	1.7	9.0
Conditional Survival Probability:			
Transplant period	.80	.75	.85
One year	.70	.60	.75
Two years	.90	.85	.94
Three years	.90	.85	.94
Four years	.90	.85	.94
Five years	.90	.85	.94
Six years	.95	.90	.97
Seven years	.95	.90	.97
Eight years	.95	.90	.97
Nine years	.95	.90	.97
Ten years	.95	.90	.97
Eleven to nineteen years	.98	.98	.98
Discount rate (%)	6.0	2.5	10.0

[a]This is identical to Table 29-2.

experience of the six centers. Table 30-3 summarizes the assumed parameter values.

5. NET COSTS TO HCFA

The medical costs of heart transplantation were estimated in Chapter 28. Table 30-4, which is a copy of Table 28-18, provides a summary of those estimates. An evaluation is assumed to cost $3,700 on net, and the average cost of the transplant procedure is about $76,000. Post-discharge costs are assumed to average about $10,000 the first year and about $6,500 in subsequent years.

The costs of alternatives to heart transplantation were described in Chapters 28 and 29. The base case estimate was an additional survival of three months without a transplant. This implies a cost of $18,453 since candidacy costs are assumed to be $6,151 per month. A second question involves the termination of Medicare benefits. When disabled Medicare-eligible individuals recover and are able to pursue "substantial gainful activity," they lose Medicare coverage. This has not been factored into the projections here. It would most likely have a minimal impact on total program costs to HCFA.

D. RESULTS

The projection results are summarized in Table 30-5. Column one is the base case: only 400 transplants are done nationwide in 1985, and Medicare-eligible individuals receive only 7.24 percent of the available organs, implying 29 transplants. Total costs to HCFA are $2.0 million dollars in 1985. By the end of 1989, there would be 93

Table 30-4[a]

Summary of Parameter Estimates for

Medical Costs to HCFA

Phase and Element	Base Case	Range Low	Range High
I. PRE-TRANSPLANT			
A. Evaluation Cost	$ 3,700	$2,700	$5,200
B. Candidacy Cost (per month)	$ 6,151	$1,000	--
II. TRANSPLANT PERIOD COSTS			
A. Survivors	$75,085	60,843	88,675
B. Decedents	$80,286	67,230	98,502
III. POST-DISCHARGE ANNUAL COSTS			
A. First Year:			
- Survivors	$ 9,535	--	$14,016
- Decedents	$11,810	--	$17,684
B. Second Year and Beyond			
- Survivors	$ 6,261	--	$ 7,975
- Decedents	$ 8,911	--	$12,750

[a]This table is identical to Table 28-18.

Table 30-5
Five-Year Projections of the Costs of Heart Transplantation Coverage to HCFA (in 1983 dollars)

I. PROJECTED NUMBER OF MEDICARE RECIPIENTS

Year	Base Case (Without Expanded Coverage)	Expanded Coverage	Expanded Coverage and Higher Volume
1985	29	400	1000
1986	32	440	1100
1987	35	484	1210
1988	39	532	1331
1989	42	586	1464

II. PROJECTED COSTS TO HCFA (in millions)

Year	Base Case (Without Expanded Coverage)	Expanded Coverage	Expanded Coverage and Higher Volume
1985	$2.0	$27.4	$68.4
1986	2.4	38.5	81.2
1987	2.7	37.1	92.8
1988	3.1	42.0	105.2
1989	3.4	47.4	118.5

III. PROJECTED SURVIVORS (end of year)

Year	Base Case (Without Expanded Coverage)	Expanded Coverage	Expanded Coverage and Higher Volume
1985	20	272	680
1986	38	519	1,297
1987	56	769	1,922
1988	75	1,024	2,562
1989	93	1,289	3,222

people in the program, including new recipients and survivors from previous years.

As described above, this assumption about a small share going to the Medicare-eligible is based on a tenuous estimate from the need analyses. If transplant programs preferred the Medicare-eligible on the basis of ability to pay, then they might obtain a larger share of the available organs. On the other hand, the nature of end-stage cardiac disease may be such that few disabled individuals live the 29 months (after disability begins) required for Medicare eligibility. (This is confirmed by the apparent difficulty the six participating centers had in obtaining the thirteen Medicare-eligible recipients to be funded by HCFA during this study.)

Column two presents the scenario of Medicare coverage for all heart transplants. That is, a program similar to the ESRD Program's coverage of kidney transplantation. Program costs increase by $25 to $44 million per year. At the end of the period, 1289 recipients are projected to be covered by Medicare, as compared with 93 under the base case.

The third column shows the impact of such expanded coverage combined with high volume of procedures. This scenario assumes a tremendous increase in the effectiveness of procurement efforts (or perhaps an improved ability to import hearts from other nations). The costs rise even more dramatically--to over $68 million in 1985, and rising to $119 million in 1989. Clearly, the assumption about the availability of organs is the most crucial one in terms of the ultimate impact on HCFA.

Other sensitivity analyses were performed using the upper bound cost estimates and the higher estimates of survival probabilities. As shown in Table 30-4, the upper bound cost parameter estimates are 20 to 50 percent higher than the base case. Using these higher costs, the resultant increase in projected aggregate costs falls in that range. For example, the base case would have 1985 costs of $2.8 million, as compared to $2.0 million, and 1989 costs of $4.8 million, as compared to 3.4 million. With upper bound costs and the scenario of expanded coverage and higher volume, the aggregate costs rise by 41 percent in 1989 to $166.8 million. (Of course, should HCFA decide to pay for cyclosporine for these patients, aggregate costs might rise by almost one-third.)

The use of higher survival probabilities (from Table 30-3) in addition to upper bound costs has little additional impact on aggregate costs. For example, costs under the base case in 1989 become $4.9 million, and under the expanded coverage/high volume scenario become $169.7 million. This is less than a two percent increase. However, with these combined alterations, the number of living recipients at the end of 1989 increases to 110 (from 93) and to 3788 (from 3222)--an increase of about 18 percent.

None of these projected scenarios achieve a steady state within a five-year period. Under the three major scenarios, average annual program cost per survivor declines from about $100,000 in 1985 to approximately $37,000 in 1989. This is still above, but approaching, the average cost per beneficiary in the ESRD Program, which had about 70,000 beneficiaries in 1982 and $2 billion in total program costs.

E. CONCLUSION; SUMMARY AND LIMITATIONS

The analysis in this chapter has projected aggregate costs to HCFA relying on (1) the assumptions on costs and survival developed in the preceding two chapters and (2) data on need and organ availability from other parts of the NHTS.

Under the base case assumptions, it appears that the coverage of heart trnsplantation would have a small impact on the HCFA budget--on the order of $2-3.5 million per year over the period 1985-89. Even with upper bound assumptions about coverage provisions and an expansion in procurement, the total costs to HCFA become on the order of $70-120 million per year. Furthermore, reasonable upper bounds on costs and survival only raise aggregate costs to the range of $96 to $170 million per year under the most costly scenario.

These projected total costs appear small, as compared to the ESRD Program, which costs over $2 billion per year. (Still, the average cost per survivor in the fifth year is above that for ESRD beneficiaries.) The thought of the ESRD Program, and its well known under-projections of aggregate program costs, gives one pause: are the upper bound assumptions truly upper bound?

This projection model and its results are not dissimilar from those of Hellinger (1982). Based also on the kidney procurement experience, he adopted three scenarios: (1) Low--250 transplants per year, (2) moderate--850 per year, and (3) high--12,000 per year. The high estimate was based on studies of hospital deaths. Hellinger assumed costs similar to the upper-bound costs used here (but in 1979 dollars); the assumed survival was also higher (46 percent at five

years post-transplant versus 37 percent in this analysis). Total program costs in the fifth year were projected to be $125 million for the scenario with 850 transplants and $37 million for 250 transplants per year. Because of the cost assumptions, these projected costs are slightly higher than those that would be projected for similar transplant volumes under the base case assumptions here. The big issue remains, therefore, the likely volume of transplants, and this depends primarily upon what happens in the procurement area.

Need appears to be much greater than organ supply. The upper bound assumption was on the order of 1,000 hearts transplanted in 1985, as compared to 172 in 1983. This upper bound assumption might be wrong for any of the following unforeseeable developments:

(1) An implantable artificial heart becomes widely available.

(2) The availability of donor hearts improves due to improvements in the procurement system (including improvements in the preservation of hearts).

(3) More hearts become available from foreign sources (i.e., outside the U.S.).

None of these developments appears likely, but they should not be forgotten.

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